REPORT
ON
GENETIC TESTING

ONTARIO LAW REFORM COMMISSION

1996

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ONTARIO LAW REFORM COMMISSION

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The Ontario Law Reform Commission was established by the Ontario Government in 1964 as an independent legal research institute. It was the first Law Reform Commission to be created in the Commonwealth. It recommends reform in statute law, common law, jurisprudence, judicial and quasi-judicial procedures, and in issues dealing with the administration of justice in Ontario.

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Ontario
Law Reform
Commission

The Honourable Charles Harnick
Attorney General for Ontario

Dear Attorney:

I have the honour to submit the Ontario Law Reform Commisison's *Report on Genetic Testing.*

December, 1996

John D. McCamus
Chair

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PREFACE

The project on genetic testing is one of four projects initiated by the Commission on the law of testing. This report constitutes the third in the series. Professor Bartha Maria Knoppers, of the Faculty of Law, University of Montreal, was appointed as Project Director. The project was commenced in the fall of 1990, although work on the project was interrupted due to the appointment of Professor Knoppers to the Royal Commission on New Reproductive Technologies. The Commission wishes to express its gratitude to Professor Knoppers for her dedication and her committment to bringing this report to fruition. The Commission would also like to express its appreciation to Professor F. Clarke Fraser, of the Department of Human Genetics, McGill University, who prepared chapter 2 of the report, and to Tom Digby and Lori Luther, who provided the Project Director with invaluable research assistance throughout the course of the project.

In addition, the Commission established an Advisory Committee, the members of which represented a wide variety of relevant professions and interest groups. The members of the Advisory Committee were: Mr. Ian Anderson, Toronto Biotechnology Initiative; Mr. David Baker, Executive Director, Advocacy Resource Centre for the Handicapped (ARCH); Dr. Janet Buchanen, Director of Molecular Genetics Laboratory, North York General Hospital; Professor Annette Burfoot, Department of Sociology, Queen's University, Kingston, Ontario; Dr. Ann Cavoukian, Assistant Commissioner - Privacy, Information and Privacy Commissioner/Ontario; Dr. Joe Clarke, Head, Division of Clinical Genetics, The Hospital for Sick Children, Toronto, Ontario; Professor Bernard Dickens, Faculty of Law, University of Toronto; Mr. Jim Faichnie, Canadian Life & Health Insurance Association; Ms. Martha Forestell, Ontario Women's Heath Bureau; Dr. Roch Khazen, Public Health Branch, Ministry of Health; Ms. Judy Koch, Disabled Women's Network—Toronto (DAWN Toronto); Dr. Sandy Lowden, Vice President and Chief Medical Director, Crown Life Insurance Company; Dr. Eric M. Meslin, Assistant Director, Centre for Bioethics, University of Toronto; Ms. Cathleen Morrison, Executive Director, Cystic Fibrosis Foundation; Dr. Jeff Nisker, University Hospital, London, Ontario; Ms. Patricia Parker, National Director of Programs, Muscular Dystrophy Association of Canada; Ms. Carol-Anne Schwarz, President, National Tay Sachs and Allied Diseases of Ontario Inc.; Dr. Donald T. Whelan, Chief of Genetic Services, Chedoke-McMaster Hospital, Hamilton, Ontario; and Dr. Ronald Worton, Geneticist in Chief, The Hospital for Sick Children, Toronto, Ontario. The Commission wishes to acknowledge the contribution of the Advisory Committee to this report, and to express its appreciation for their time and their insights.

Finally, the Commission wishes to express its appreciation to J.J. Morrison, Senior Counsel at the Commission, for his involvement throughout the course of the project.

The research underlying this report is complete as of December 31, 1995.

CHAPTER 1

INTRODUCTION

The metaphor of precolumbian cartographers has been used to describe the limits of the new genetic map where, contrary to the old maps, no dragons mark the edge of the unknown "terra incognita".[1] Today, knowledge must anticipate and plan for the real monsters—the value conflicts that the knowledge of the new human genetics produces.

Genetic technology, has been touted as one of the great revolutions of medicine. The Human Genome Project (HGP), an audacious fifteen-year, $3 billion dollar effort that will map and sequence the genetic makeup of humans, may render population screens, diagnostic tests, and therapies a commonplace happenstance as early as the next decade. Progress, in fact, has outstripped expectations and the project may be completed as early as 2003. Technologies developed in response to the effort have already quadrupled the rate of discovery of human disease genes.[2] Conservative estimates indicate that approximately 50,000 gene markers will be developed.[3] Moreover, it has been noted that "[e]ventually a new gene will be sequenced, that is, have the order of its chemical subunits determined, every hour".[4]

The results of these discoveries however, are often fraught with uncertainty. While genetic tests can be used to predict the incidence of single gene disorders with seeming relative ease, these monogenic diseases are proving to be not so "simple" after all. Moreover, few precise tests exist for disorders caused by mutations in several genes, or for diseases brought on by interactions between an individual's genes and his or her lifestyle or environment—that is, multifactorial/polygenic conditions, the most common diseases. In the case of cancer, for example, mutations in five separate genes are known to increase an individual's susceptibility to colon cancer while mutations in at least two genes are known to predispose breast cancer. However, the absence of such mutations does not necessarily mean that the person who has been screened will not develop either disease.[5]

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1 Annas, "Mapping the Human Genome and the Meaning of Monster Mythology" (1990) 39(3) Emory Law Journal 629.

2 T. Beardsley, "Vital Data" (March,1996) Scientific American 100-105 at 100. (hereinafter "Vital Data").

3 P.J. Boyle, "Shaping Priorities in Genetic Medicine" (1995) 25(3) (Special Supplement) Hastings Center Report S2- S8 at S2.

4 Vital Data, *supra*, note 2 at 100.

5 A. Abbott, "Complexity Limits the Powers of Prediction" (1996) 379 Nature 390.

For example, twenty-five percent of the one in ten women in Western society likely to develop breast cancer by the age of eighty-five, will die from the disease.[6] About five percent of these cases are hereditary.[7] The mutation in the two known susceptibility genes—BRCA1 and BRCA2—account for approximately eighty percent of all the hereditary cases. As a result, genetic tests for BRCA1 and BRCA2 will not be of any value to the remaining twenty percent of women predisposed to hereditary breast cancer, and will be even less informative for the ninety-five percent of cases that are not hereditary.[8] Testing therefore, in view of the large number of genes and mutations, will be of potential help only to those in high-risk families.

Notwithstanding the probabilistic nature of genetic testing—that is, that a certain gene may increase only the *likelihood* of developing a disease—the oncoming tidal wave of genetic data is nonetheless fast approaching. As opportunities to predict, cure, and prevent disease become (seemingly) possible, and as the availability to, and public awareness of, genetic testing increase, more and more persons will seek out testing in the future. Preimplantation genetic testing will offer future parents the opportunity to evaluate embryos and implant only those that are not affected by disease. Prenatal genetic testing will enable parents to continue a pregnancy, or to prepare for, or avoid, the birth of a child with particular genetic characteristics. Each of us will be able to be tested for diseases to which we are susceptible or predisposed, and thereby obtain information that will help us prepare for the condition well before its onset by adjusting lifestyles, or seeking preventive or prophylactic therapies. Indeed, the development of new genetic therapies may promise effective treatment for many otherwise intractable diseases.[9]

Irrespective of the moral and ethical issues raised by new genetic technologies, (for example, the preselection of embryos, the possible manipulation of germline cells, or, one day, the genetic enhancement of persons), undoubtedly, the underlying goal of the HGP is to benefit mankind. To do so however, the advances in medical genetics must outweigh the potential for harm. Although the intent of the HGP is to defeat not only diseases long known to be inherited, but also those with a more subtle genetic link, potential abuses of this new genome science are possible.[10] The number of possible abuses of genetic information—denial of insurance, discrimination in employment, or an increase in litigation, to name but three—warrant caution.

Currently, enough is not known about the effects of mutations. Much remains to be done in understanding not only how different mutations in individual genes lead to a particular disease but also how disease can result from an interaction of genes and

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6 *Ibid.*

7 *Ibid.*; J.R. Korenberg et. al., "Medical Genetics" (1995) 273 :21 JAMA 1692-3

8 *Ibid.*; see also, Vital Data, *supra* , note 2 at 102.

9 Boyle, *supra,* note 3; J.R. Korenberg et. al., *supra*, note 7.

10 Vital Data, *supra,* note 2.

environment. Thus, genetic data currently available can open the door to discrimination. In the past, discrimination was largely confined to members of families visibly afflicted with rare conditions showing a clear pattern of inheritance. However, as the number of genetic tests grow, it will happen on a larger scale "since we're all at risk for something",[11] and since the presence of certain genes in all individuals makes each person—affected or unaffected—a potential victim of discrimination.

Genetic discrimination has the potential to become a widespread phenomenon. An argument has in fact been made that a new rubric of harm be created, that of "geneticism".[12] This position is based on the contention that the explosion of genetic knowledge and proliferation of genetic tests may lead people into seeing individuals as their genes, subdivide communities by their genetic characteristics, and promote the idea that genetic differences are real, biological and neutral grounds for different treatment; something akin to the pervasive harm of racism and sexism.[13] One commentator has argued as follows: [14]

> Combating individual instances in which a person of color was treated differently because of race, or a woman treated differently because of her sex, will not uproot deep widespread racism and sexism. Similarly, condemning individual instances of genetic discrimination will do little to address systematic genetic categorization, a world view that seeks to sort people by their genetics, and the conviction that supposedly deviant genes merit different treatment.

An attempt to forestall discrimination and prevent people with genetic predisposition to disease from being considered deviant, may be the elaboration of a new category of inherent qualities in human rights legislation like race and sex, that is, genetic characteristics. This route, however, is fraught with difficulty given the possibility that it may promote further stigmatization by singling out what is genetic from other medical information.

Interestingly, a questionnaire, sent to 127,790 people from "disease" associations and families, who, though free of symptoms, were considered at risk for acquiring a genetically based illness, indicated that of the 917 persons who self-selected to respond, 455 had been discriminated against by either health or life insurance companies, health care providers, blood banks, adoption agencies, the military, or schools, after they had revealed a genetic diagnosis. Some indicated that the alleged instances of discrimination also impacted asymptomatic relatives.[15] Billings maintains that "the public will reject genetic testing out of a fear of discrimination"[16] and this even when such testing would be medically valuable. Yet,

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11 *Ibid.*, at 102.

12 S.H. Wolf, "Beyond 'Genetic Discrimination': Toward the Broader Harm of Geneticism" (1995) 23 Journal of Law, Medicine & Ethics 325.

13 *Ibid.*, at 346.

14 *Ibid.*, at 347.

15 L.N. Geller, J.S. Alper, et al., "Individual, Family, and Societal Dimensions of Genetic Discrimination: A Case Study Analysis" (1996) 2(1) Science and Engineering Ethics 71-88.

16 Vital Data, *supra* , note 2 at 103.

at the same time, this study admitted that "[i]t is also possible that the [low] response rate reflects a real result; that while genetic discrimination exists at this time it is not a widespread phenomenon".[17]

Many issues need to be addressed. What are the ethically justifiable uses of genetic tests? Who should have access? Who should pay? Who should decide—what and when? Will the use of genetic information lead to more discrimination in insurance and employment or towards the disabled generally? Who controls or "owns" genetic information and material? What are the moral or legal obligations of the State, of physicians, of individuals to family members, of potential parents to future children, of data banks or laboratories? Can genetic counselling remain non-directive? In short, will the availability of diagnostic tests before conception, in *utero,* and after birth, lead to selection, elimination, manipulation, discrimination and litigation or to better information, communication, individualization, socialization, and comprehension of human nature through education?

The most fundamental issue therefore is how to use this new genetic knowledge responsibly, in order to understand better "what it means to be human".[18] Open discussion must be encouraged so that we can decide legitimately what direction scientific research and the utilization of this wealth of scientific knowledge should take.

An appropriate commentary on recent developments in bioethics generally, made with respect to the twelve member states of the European Community, provides that the first generation of human rights—political and civil—is leading to the emergence of the recognition of social rights in the second, towards a new third generation, that of "human rights adequate to this technological era, including informed bioethics to guide research and development in the life sciences".[19] The right to respect for human dignity, to individual autonomy, to enjoy the benefits of scientific progress, to the highest attainable standard of health, to privacy, to reproductive liberty, and to freedom from discrimination, are basic human rights that may be limited when collective rights are at stake or when public policy dictates that in a free and democratic society certain limits must be set. Moreover, the interpretation of the ambit of these rights may well be different in view of the transgenerational effects of genetic decision-making. The impact of the use or misuse of knowledge derived from genetic testing on human rights as currently interpreted and filtered through the *Canadian Charter of Rights and Freedoms* and the Ontario *Human Rights Code* remains to be seen (Chapter 3).

On an international, national, and provincial level, the characterization of human genetic material down to its very substrate—the DNA—is a crucial legal and ethical issue. The classical division of law is between persons and property. Can banked DNA, pathology samples, samples taken for paternity testing or newborn screening, samples found in

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17 *Supra*, note 15 at 83.

18 Annas, *supra*, note 1 at 661.

19 J. Elizade, "Bioethics as a New Human Rights Emphasis in European Research Policy" (1992) 2 Kennedy Institute of Ethics 159-169 at 166.

"abandoned" hair or in a buccal swab, or samples "leftover" after treatment, be considered the "property" of the person? Can it be devised by will, or sold, or patented where it has certain characteristics?

It may be more respectful of the dignity of the person to consider the interest in one's DNA as a personal right that is part of one's physical and mental integrity and security. Currently property law may offer greater legal control. Yet, it is the genetic information extracted from the material by different techniques as it relates to a particular persons' DNA that makes it "personal".[20] The policy issues raised by any eventual recommendations will be indicative of the respect accorded not to "DNA" *per se* but rather to personal privacy and inviolability. They will also recognize and protect the free and informed participation of the person in genetic research, testing, and therapy (Chapter 4).

Issues of personal privacy may be constrained by the fact that genetic testing can establish familial relatedness with virtual certainty. As a result, our expanding notions of the family may also be limited by the emphasis that DNA testing places on biology.[21] Can one (typically the putative father) be required in the interests of the child or the economic interests of the State to take a paternity test so as to enforce maintenance obligations? Should the biological truth of parenthood outweigh the best interests of the child? Whether, in fact, the scientific imperative of biological truth is in the best interests of all parties concerned warrants further consideration (Chapter 5).

Few implications of the HGP, however, have received as much heated debate as those that concern insurance.[22] An individual's genetic profile can provide important information about his or her future state of health and as such has a direct bearing on actuarial calculations regarding health and life expectancy.[23] The insurance industry claims that access to such genetic information is essential for the calculation of equitable premiums.[24] Critics of the industry warn of the undesirable effects that unregulated access could create.[25] Should genetic

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20 See L.B. Andrews, "My Body, My Property" (1986) 16:5 Hastings Center Report, 28-38; J. Horton, "A Personhood Analysis of Property Rights in the Human Body " (1995) 11(2) Canadian Intellectual Property 213.

21 See T. Caulfield, "Paternity Testing in the Genetic Era" (1996) Health Law in Canada (forthcoming); *Goudie v. Goudie* (1993) B.C.J. No. 1049 (QL).

22 Briefing, "Gene Tests: Who Benefits from Risk?" (1996) 379 Nature 389-392; Correspondence, "Genetic Testing and Insurance" (1996) 380 Nature 384-6.

23 "Whose Right to Genetic Knowledge" (February 1,1996) 379 Nature 379 (hereinafter Nature).

24 K.A. Clifford & R. P. Iuculano, "AIDS and Insurance: The Rationale for AIDS-Related Testing" (1987) 100:7 Harvard Law Review 1806; N.A. Holtzman, Proceed with Caution: Predicting Genetic Risks in the Recombinant DNA Era (Baltimore: Johns Hopkins University Press, 1989).

25 See M. Wadman, "House Backs Curb on Genetic Information" (April, 1996) 380 Nature 374 who reports that the United States House of Representatives passed a bill preventing health insurers from using genetic information to exclude potential clients. Despite this attempt at control, Neil Holtzman pointed out that a big loophole exists in that insurers, if the bill were to become law, would (still) be free to demand high rates for those who show genetic predisposition to disease. See also, C.L. Earley & L.C. Strong, "Certificates of Confidentiality: A Valuable Tool for Protecting Genetic Data" (1995) 57 Am. J. Hum. Genet. 727-31

information be made available to the insurance industry? Should they be allowed to ask prospective policyholders to undergo genetic tests as a condition for taking out an insurance policy? Is accessibility to life, disability, or mortgage insurance an entitlement, that is a socio-economic right, or is it simply a privilege?

Difficulties exist not only with regard to the probabilistic nature of genetic information but more specifically with respect to actuarial calculations of morbidity and mortality, given the unknown impact of environmental factors on genetic predisposition to disease. Insurers are worried about "adverse selection"—that is, where an individual finds through a genetic test that he or she has a high chance of developing a life threatening disease in the future and takes out a large insurance policy on standard terms without disclosure of this information.[26] At the same time, there are ethical dilemmas for those who may prefer not to know the results of such tests. While a short moratorium on the use of genetic information by insurers may be advisable, in the end, both the insurer and the policyholder will have to share information equitably since there is no long term alternative to permissible discrimination[27] by a private industry within the limits of the law (Chapter 6).

Similarly, though to a lesser extent, employers may claim legitimate discrimination and select future employees within the broad scope of human rights legislation. They may also use medical tests as a criterion of measuring job fitness, and to monitor the effects of the workplace environment. The question arises whether genotype discrimination is a species of discrimination on the basis of disability. In 1995, the American Equal Employment Opportunity Commission (EEOC) stated that persons who were presymptomatic for, or predisposed to, a disabling disease (rather than actually being disabled) would be protected under the *Americans with Disabilities Act of 1990* (ADA), as a perceived disability.[28] It is unclear however, whether this interpretation will be upheld by the courts.

In Canada, human rights codes arguably provide protection against discrimination based on disability.[29] According to the 1991 Science Council of Canada report, genetic testing should not become a substitute for a clean and safe work environment.[30] Under law, employers are responsible for the health and welfare of their workers. The imposition of

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(hereinafter, Certificates of Confidentiality).; For a response to this article see, J.A. Lowden, "Certificates of Confidentiality", (1996) 58 Am. J. Hum. Genet. 437-8

26 Nature, *supra*, note 23; N.A. Holtzman, *supra*, note 24; and The American Council of Life Insurance and the Health Insurance Association of America, Report of the ACLI-HIAA Task Force on Genetic Testing (Washington, DC: 1991).

27 Nature, *ibid.*

28 M.A. Rothstein, & B.M. Knoppers, "Legal Aspects of Genetics, Work and Insurance in North America and Europe" (1996) 3:2 J. Health Law (in press).

29 See *Fontaine v. CP Ltd* (1989) 11 C.H.R.R. D/288 affirmed (1990) 91 C.L.L.C. 17,008 (Fed. C.A.) where an HIV positive asymptomatic condition has been considered a disability. Also, human rights legislation characterize disability or handicap in terms of an existing impairment, a history of impairment or a perceived impairment. See also federally, *Levac v. Canada* (Armed Forces) (1992) 15 H.R.R. D/1750.

30 Science Council of Canada, Genetics in Canadian Health Care (Ottawa: Supply & Services Canada, 1991).

"reasonable" genetic tests on prospective employees would be permissible currently, as long as the tests are scientifically valid and reliable and relate directly to the employment in question.[31] For the employer, traditional defences of bona fide occupational requirement and undue hardship must be substantiated. A review of the pertinent legislation indicates that an interpretative ruling may be required so that definitions of handicap and perceived disability apply to both genetic susceptibility and genetic predisposition without distinction. Safeguards are needed since genetic testing will more and more reveal individuals who are only carriers, or susceptible only in certain environments, or, predisposed, but only for a late onset disorder, that is, genetic testing will expose the "healthy ill" (Chapter 7).

The accessibility, availability, and marketing of genetic testing will undoubtedly increase the likelihood that patients will know about, and ask for genetic tests, thereby incrementally moving these tests towards the set of "standard" diagnostic tools.[32] Health care professionals who perform genetic testing have a duty to inform their patients of the availability and results of such standard tests and this notwithstanding that much of the information is couched in the language of probabilities, susceptibilities, and risk factors.[33] Physicians also are responsible for the care and treatment of their patients. With the advent of new medical and genetic technologies, this duty of care now arises even prior to conception given the availability of testing and the possible need for genetic counselling. How far does the duty to treat and inform extend? Does this duty extend to routine genetic testing for prospective parents who are carriers or at risk, and does it include experimental therapy *in utero* for those conditions where birth would be too late to treat effectively or, even to testing for susceptibilities or for late onset disorders?

The duty of health care professionals to (competently) perform genetic testing and inform with due care is subject to general malpractice rules. Wrongful birth actions (taken by the parents) and wrongful life actions (taken by a child born with a genetic condition) are available and have just recently been relied upon for genetic malpractice suits in Canada.[34] Given the additional legal obligations imposed on physicians, not to mention the ethical

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31 *Ibid.*; Committee on Assessing Genetic Risks, Institute of Medicine (L.B. Andrews et. al., eds.) Assessing Genetic Risks: Implications for Health and Social Policy (Washington, DC: National Academy Press, 1994) at 24.

32 J. E. Bickenbach, " The Human Genome Project and Health Law: Genetic Discrimination" Genetics and the Law Symposium October 21, 1995, Osgoode Hall, Toronto.

33 See, generally, Health Law Institute, University of Alberta (1995) 3 Health Law Journal, Special Edition "Professional Norms in the Practice of Human Genetics".

34 See D. Roberts, "Parents Sue Doctor over Abnormal Son: Claim Boy Shouldn't have been Born", Globe and Mail (September 7, 1994) at A1 where a wrongful life suit was instituted against a physician, the claim being that the child should never have been born and that had the MSAFP screen been correctly interpreted the parents could have had the chance to decide whether to continue the pregnancy or abort and prevent the birth of a severely disabled child; and B. Branswell, "Parents of Dying Boys Sue Doctors Over Genetic Disease" The Gazette (May 16, 1996) at A11 where parents of two Ottawa boys have instituted a wrongful birth action against three doctors claiming that they were not properly told of the risks that their children would be born with muscular dystrophy and doctors were earlier informed that the mother's brother had died from Duchenne muscular dystrophy. The physicians argue that from what was known at the time of the assessment, they did not act improperly.

implications of such actions, wrongful life suits are prohibited in some American States.[35] It is possible that, in the absence of parental immunity, such suits could be taken by children against their parents.

Issues of due care, testing and informing are of special concern with regard to vulnerable populations such as newborns, children, adolescents and incapable adults. The participation of children and minors in genetic testing and research raises a host of issues concerning the limits and extent of parental authority and the rights of the children and minors involved. Generally, it is agreed that genetic testing for children and minors is appropriate only when a clear and timely benefit, in terms of treatment or prevention, exists.[36] Should children be tested for the benefit of others? Should they be subject to presymptomatic or susceptibility testing? What recourses are available for decisions made prior to their conception or while *in utero* by health professionals and by their parents? Can the State in its *parens patriae* function of protecting "incapables" become the protector of children and override what can be seen as legitimate parental decision-making? (Chapter 8)

Paradoxically, whatever legislative limits may be set on genetic testing or on access to genetic information, such limits may well be circumvented in that genetic information may already be available in the persons' record in the physicians' office. While generally, confidentiality of medical information is an international ethical and legal norm,[37] and is inherent in the fiduciary nature of the physician-patient relationship,[38] different legal constraints apply with regard to its accessibility depending on where such information is gathered, by whom, with what consent and under what circumstances (research, therapy, pedigree studies, screening programs, pilot projects, etc.). This disparity in the treatment of medical information merits particular attention since this is where genetic information is currently being gathered and stored.

In addition, genetic information has features that make it more than just extremely sensitive medical information. It is necessarily familial and transgenerational. Its history and link with eugenic selection and "handicap" make it socially stigmatizing. It is also uniquely individual and identifying and yet, to be useful, must be stored over time, even beyond the lifetime of a person. It has reproductive consequences and, in almost all cases today, genetic information is probabilistic and not linked to the availability of any therapy. Finally, it sometimes runs along racial and ethnic lines or regional isolates giving it further discriminatory potential—discrimination by association. Traditional privacy, confidentiality,

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35 See L.B. Andrews, Medical Genetics: A Legal Frontier (Chicago: American Bar Foundation, 1987; E.W. Clayton, "Reproductive Genetic Testing: Regulatory and Liability Issues", (1993) 8 (Suppl) Fetal Diagn Ther. 29-59.

36 American Society of Human Genetics and American College of Medical Genetics, "Points to Consider: Ethical, Legal and Psychosocial Implications of Genetic Testing in Children and Adolescents" (1995) 57 Am. J. Hum. Genet. 1233-41; D. Wertz, J.H. Fanos & P.R. Reilly, "Genetic Testing for Children and Adolescents: Who Decides?" (1994) 272 JAMA 875-880.

37 Z. Bankowski & A.M. Capron, Eds., in Proceedings of the 24th CIOMS Round Table Conference, The Inuyama Declaration (CIOMS, Geneva, 1991).

38 *McInnervey v. MacDonald* (1992) 2 S.C.R. 138.

and accessibility rules will in all likelihood need to be reformulated in light of these features.[39] Moreover, issues of disclosure, particularly with respect to at-risk relatives, need to be considered. Although no courts have held that there is a duty on physicians or on family members to warn relatives of their genetic risks,[40] if such a duty is established as the standard of care, then many more issues will have to addressed, including how to maintain confidentiality of the original participants, which relatives need to be contacted, how many relatives must be contacted, how much effort must be used to locate relatives, and how much genetic counselling must be given to the individuals contacted.

The promotion of "genetic-specific" privacy legislation could well create inconsistencies in the dissemination of medical information and provide inadequate protection for other medical (nongenomic) information. As medical records become computerized, it will become increasingly difficult to limit transmission of data to specific information only. Disparate privacy and security standards may be unwise and impractical. Comprehensive privacy legislation in relation to all medical information, with additional safeguards for genetic information if necessary, may be a sound approach.[41] In this way, "genetic privacy" can be considered as a subset of personal data protection within the larger right of informational self-determination (Chapter 9).

Five basic principles are emerging from proposed ethical frameworks for the integration of knowledge emanating from the Human Genome Project: autonomy, privacy, justice, equity, and quality, and this out of respect for human dignity.[42] Only a comprehensive evaluation of these principles, of the impact of genetic testing and information, and of the social risks of intervening or not in an environment that is cognizant of scientific facts and not fiction will erase the dragons from the "genomic map" to replace them with realistic and compassionate human boundaries mindful of our obligations to others and to future generations.

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39 M.J. Mehlman et al., "The Need for Anonymous Genetic Counseling and Testing" (1996) 58 Am. J. Hum. Genet. 393-97; Certificates of Confidentiality, *Supra*, note 25.

40 L.B. Andrews, (1991) 64 Legal Aspects of Genetic Information 29-40; J. Sestito, "The Duty to Warn Third Parties and AIDS in Canada" (1996) 16:3 Health Law in Canada.

41 L.O. Gostin, "Genetic Privacy" (1995) 23 J. of Law, Medicine & Ethics 320-30 at 326.

42 B.M. Knoppers and R. Chadwick, "The Human Genome Project: Under an International Ethical Microscope", (1994) 265 Science 2035.

CHAPTER 2

TYPES OF GENETIC TESTING

1. INTRODUCTION

The recent revolution in DNA technology has transformed biology, and genetics in particular, to the point where possibilities undreamed of are now coming to be. One of the most awesome is the *mapping* of the human genome, where every known gene will be assigned to its particular place on a particular chromosome.[1] As the number of identified genes increases, so does the potential for practical applications of this knowledge, and the complexity of the social implications.[2] One of the applications is genetic testing.

Genetic testing may be done for medical, reproductive, or non-medical purposes. It can be done after birth or prenatally. *Genetic testing for medical purposes* is the analysis of the genetic material to identify differences that determine whether an individual has, or will develop, a particular disorder, or has an increased probability of doing so. The term may also refer to biochemical or immunological tests for conditions resulting from a particular genetic difference (for example, blood group or metabolic disorder) rather than analysis of the genetic material. That is, the test may be done on the biochemical *phenotype* rather than the *genotype.*

Genetic testing for reproductive purposes is intended to determine whether a person, or couple, carries a genetic difference that may increase the probability that their child will have a genetic disorder (disease or malformation). Prenatal genetic testing determines whether the fetus has, or will have, a genetic disorder. Genetic testing for non-medical purposes is the analysis of an individual's array of normal genetic variations in order to establish the person's identity—for forensic purposes, for determining whether twins are identical or fraternal, for paternity exclusion, for establishment of family relationships, or for population genetics studies.

The following section will provide a brief description of the genetic material—genes and chromosomes—how it produces genetic disorders, and how genetic differences are revealed by testing.

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1 Collins and Galas, "A New Five-Year Plan for the U.S. Human Genome Project" (1993), 262 Science 43-46.

2 Juengst, "Human Genome Research and the Public Interest: Progress Notes from an American Science Policy Experiment" (1994), 54 Am. J.Hum. Genet. 121-128.

2. THE GENETIC MATERIAL AND HOW IT WORKS

(a) THE DNA—STRUCTURE AND FUNCTION[3]

The body is made up of *structural proteins* that constitute its substance (for example, muscle, collagen, keratin, and hemoglobin) and *enzymes*—proteins that act as catalysts for the biochemical reactions of metabolism and development. The proteins are made up of long chains of *amino acids*. The sequence of amino acids is specific for each protein and determines its structure and, thereby, its function. This sequence of amino acids is determined by the DNA (desoxyribonucleic acid), the genetic material.

The DNA is contained in the nucleus of the cell. It is like a rope-ladder, the rungs being pairs of *nucleic acid bases,* named guanine (G), adenine (A), cytosine (C) and thymine (T). In order for the rungs to fit, wherever there is an A on one strand there is a T on the other, and across from a G there is a C—a complementary relationship.

The sequence of bases in the DNA determines the sequence of amino acids in the protein. Specifically, a particular sequence of three base pairs (a triplet) in the DNA codes for a particular amino acid in the protein. This is the genetic code, which is virtually universal. Thus each protein has a sequence of base pair triplets somewhere in the DNA that determines its amino acid sequence, and thereby its structure, and thereby its function. That particular piece of DNA is the gene for that particular protein. (Some proteins have several components, or polypeptides, in which case there is a gene for each polypeptide.) For many proteins the exact DNA base pair sequence is known. Because of the human genome project the number of sequenced genes is growing rapidly.

The gene functions by producing a messenger RNA (ribonucleic acid), which has a complementary relationship to the DNA, and thus the code for its particular protein. The mRNA migrates from the nucleus to the cytoplasm of the cell, where it organizes the synthesis of amino acids in the correct sequence.

Only a minority of the DNA codes for proteins. The function of the non-coding DNA is not well understood, but is involved with the regulation of the coding DNA, that is, switching genes on or off at the right time.

(b) THE CHROMOSOME

A chromosome is the vehicle that carries the DNA. It is a microscopically visible body composed of a continuous strand of DNA and a protein framework. Each chromosome has a characteristic size, shape and, with modern staining techniques, a characteristic pattern of banding. In human beings, each body cell has two sets of twenty-three chromosomes, one set from the mother, the other from the father. The body grows by cell division. When the cell divides (mitosis) the chromosomes replicate—the old and new copies separate, one to each of

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[3] See, generally, Nora and Fraser, *Medical Genetics: Principles and Practice* (4th ed., 1994).

the new cells, so the two new cells each get a complete set of twenty-three pairs. When the cells that give rise to the gametes (sperm and egg) form, each chromosome pairs with its partner, and then the pairs segregate (meiosis, or reduction division), so that each gamete gets *one* complete set. After fertilization of the egg by the sperm the new organism will have two sets of chromosomes again.

3. GENETIC VARIATION IN THE CHROMOSOMES—ANEUPLOIDY

If there is a mistake in pairing or segregation, one new cell may get both members of a pair, and the other one neither. After fertilization, the resulting individual may have three of that particular chromosome (as in trisomy 21, or Down syndrome) or only one (as in XO Turner syndrome). Absence, or excess, of chromosomal material means confusion in the genetic information, resulting in widespread abnormalities of development.

Modern techniques can detect not only extra or missing whole chromosomes (aneuploidy), but very small missing bits (deletions), extra bits (duplications), or rearrangements (inversions, translocations). Rearrangements do not affect development, since all the genetic material is there, but they may lead to an unbalanced chromosome complement in the offspring of a carrier.

4. GENETIC VARIATION IN THE DNA—MUTATION

When the DNA replicates, sometimes there are mistakes in the copying process, so that the new DNA strand has a base pair change. Most of these mistakes are corrected, but occasionally one slips through and becomes a new genetic variation, or *mutation.* The base pair change may interrupt synthesis of the corresponding protein, or cause one amino acid to be changed, which may alter the structure and function of that protein, which, in turn, may lead to a genetic disorder. In other cases the base pair substitution has no effect on protein function, and may persist simply as a variation in the DNA, a genetic *marker,* useful for identification of individuals, and mapping the chromosome. Mutations may also result from *deletions* of one or more base pairs, too small to be seen microscopically.[4]

5. MUTANT GENES MAY BE RECESSIVE OR DOMINANT

Every individual gets a set of genes from each parent, so the genes are paired. When an individual carries one non-mutant form of a particular gene and a mutant form that results in an absence or inactivity of its protein, the activity of the protein in the carrier of the mutant gene will be reduced by half. If the protein is an enzyme, reducing its activity by half will usually not interfere with its function. The non-mutant gene produces enough enzyme to do the job, and the individual is unaffected. The mutant gene is therefore said to be *recessive* to the non-mutant form, since it does not express itself in the presence of the non-mutant form. It is only when a child gets the mutant gene from both parents (who obviously must both be carriers) that there is no normal protein to do the job and the child will have a disorder, the

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[4] *Ibid.*

nature of which will depend on the function of the inactive protein. For example, an albino child lacks the enzyme tyrosinase, which catalyses the synthesis of the pigment melanin. It has inherited an inactive tyrosinase gene from each of its normally pigmented parents, and cannot make skin or hair pigment. Since there is one chance in two that the child will receive the mutant gene from each parent, there is one chance in four that it will inherit the mutant gene from both of them, and be affected.

Alternatively the mutant gene may code for a structural protein, and render it abnormal in structure. In this case, a person who has one mutant and one non-mutant gene makes a mixture of normal and abnormal protein, and will have a disorder, again depending on what protein is involved. For example, there is a gene that controls the structure of a particular type of collagen. Carriers of a mutant and a non-mutant gene for this collagen will have a mixture of normal and abnormal collagen, which may result in brittle bones—a disorder called osteogenesis imperfecta. Since persons carrying only one mutant gene show its effect, the mutant gene is said to be *dominant* to the non-mutant gene. An affected person will transmit either the mutant or the non-mutant gene to the child, who will therefore have a fifty-fifty chance of being affected. If an affected person has inherited the mutant gene from a parent, that parent will be affected. Sometimes the mutation will occur in the sperm or egg giving rise to the individual, and that individual will be affected but will have unaffected parents.

6. TESTING FOR VARIATION AT THE DNA LEVEL[5]

(a) DNA PROBES

Recent advances in molecular genetics have greatly expanded the scope and sophistication of genetic testing at the DNA level. This expansion has been made possible by the emergence of three important techniques: (1) the ability to *sequence* the DNA; (2) the use of *restriction enzymes,* each of which cuts the DNA at a specific sequence; and (3) the ability to *amplify* specific DNA sequences from very small amounts of DNA. This technique, known as PCR, for polymerase chain reaction, has revolutionized biology. From the DNA of even one cell, a particular gene can be amplified exponentially, to an amount sufficient for sequencing, or testing for variation, or put into a bacteria or other vehicle for unlimited replication (*cloning*).

As already noted, DNA is a double-stranded molecule, with the strands being connected by rungs of nucleic acid base pairs, and there is a specific complementary relationship between the bases: A on one strand must pair with T on the other, and G with C. This makes it possible to create *probes* for any gene, or part of a gene, for which the base pair sequence is known. Short chains of DNA or RNA can be synthesized with a particular base pair sequence complementary to that of the gene in question. This can be used as a probe, that will bind to the base pair sequence of that particular gene, and nowhere else. By attaching a label, radioactive or fluorescent, to the probe, it is possible to identify a particular gene sequence either in the digested DNA, spread on a gel, or directly on a chromosome, spread on a

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[5] See, generally, *ibid.*

microscope slide. (When the probe is labelled fluorescently, the spot on the chromosome where the probe has bound to the gene lights up, as a coloured dot. This is known as fluorescence in situ hybridization, or FISH.)

Probes can be used to detect mutant genes when the mutation involves an alteration in a particular base pair. Because there is a base pair mismatch, the probe for the normal gene will not bind as well to the mutant gene as it does to the normal gene, whereas a probe that corresponds to the mutant gene will bind better to the mutant gene. This approach can be used for carrier detection or prenatal diagnosis. There are problems, however. One is *genetic heterogeneity*; the mutational base pair difference may exist in different parts of the gene in different families. This means that a probe that may be diagnostic in one family may not be in another. This is a major problem with screening for genetic disorders. For example, the most common mutation in the cystic fibrosis (CF) gene represents only about seventy percent of all CF mutations, so using only this probe would lead to many false negative tests. Similarly for the breast cancer genes, and many others. This is not a problem when testing within a family, once the mutation has been identified.

(b) DNA Markers

One of the surprises provided by progress in molecular genetics is that the genetic material is far more variable than expected. One example of this variability is the DNA polymorphisms. A *polymorphism* is a genetic variant that is common enough to be useful for mapping and population studies.

(i) Restriction Fragment Length Polymorphisms (RFLPs)

A restriction enzyme cuts the DNA at a specific sequence, called a recognition site. There are hundreds of restriction enzymes, each recognizing only a particular sequence. Thus, the enzyme EcoRI will cut the DNA only where there is the sequence GAATTC. The recognition sites are distributed throughout the genome. If a sample of DNA is digested with EcoRI, the enzyme will cut it into approximately a million fragments, of various lengths. The digest is put on a gel in an electric field, and the fragments spread out according to size. The spread is then transferred by direct blotting to a filter paper (a "Southern blot"). If a radioactive probe for a particular DNA sequence is placed on the filter paper it will bind to the DNA fragment that contains that sequence, thus labelling the fragment's place on the spread. There will, of course, be an EcoRI recognition site at either end of the fragment. If one of these recognition sites is changed, by mutation, so that the restriction enzyme does not recognize it, the length of the fragment will be extended to the next EcoRI recognition site, and the fragment will be bigger, so it will end up at another place on the gel. Here, then, we have a genetic difference—length of a particular restriction fragment—that has no functional significance, but can act as a genetic marker, illustrated simply by the position of a band on the Southern blot. These genetic differences are quite frequent, and a locus may have several variants—that is, the loci are polymorphic. Thus the name Restriction Fragment Length Polymorphism—DNA markers that are useful for mapping genes, as well as establishing identity, as we discuss below.

(ii) Variable Number of Tandem Repeats (VNTRs)

A second kind of DNA marker is the VNTRs—Variable Number of Tandem Repeats. VNTRs are sequences of eleven to sixty base pairs that are repeated several times. The number of repeats is variable, with up to several dozen alleles; one person might have five repeats and another three at a particular locus. The DNA restriction fragment containing that locus would therefore be bigger in the first person than in the second, and would migrate to a different position on the Southern blot. Thus we have a normal genetic marker, demonstrable by analysis of the DNA. There are many of these markers distributed throughout the genome. Because they are so variable, they are more useful than RFLPs for mapping, and in forensic medicine and paternity testing—as in "DNA fingerprinting", discussed below.

(iii) Simple Sequence Repeats (SSRs)

In the newest type of DNA marker, the Simple Sequence Repeats, the repeat sequences involve only a few nucleotides. Again, the repeat sequences vary in length, are very polymorphic, and are widely distributed throughout the genome.

7. TESTING FOR VARIATION AT THE CHROMOSOME LEVEL

Testing at the chromosomal level is used for diagnosis of children with developmental problems, for testing of individuals in families in which a chromosomal rearrangement increases the chance of a chromosomal disorder, and for prenatal testing in groups in which there is an increased probability of a chromosomal disorder—for example, in pregnant women over the age of thirty-five. It is done by microscopic examination of the chromosomes or sometimes, more recently, by FISH. Because chromosomal genetic testing is very sensitive and specific, is not useful for personal identification, and does not reveal predisposing genes, it raises fewer social and ethical concerns than does testing at the DNA level.

8. GENETIC TESTING FOR MEDICAL PURPOSES

Genetic testing is done to confirm the diagnosis in children with a suspected genetic disorder, or to detect a genetic disorder before it appears clinically. Where therapy or preventive measures are available, the aim is to prevent the harmful effects of the disorder. Where prevention is not available, the aim of testing may be to help the individual, or the parents, to prepare themselves for the onset of the disorder, both psychologically and practically. As the same tests are done for both groups, there seems little point in discussing them separately, especially when new therapeutic advances are moving disorders from the second group into the first.

(a) Neonatal Screening

Neonatal screening is the mass screening of newborn infants to detect genetic disorders as early as possible after birth (current usage recommends the use of the term "screening" for testing on a population basis, although this usage is not always adhered to strictly).

Neonatal screening is usually restricted to conditions where therapeutic or preventive measures will allay the damaging effects that will occur if the disorder is untreated. These include phenylketonuria (PKU) and galactosemia, which are treated by the early provision of a special diet; congenital hypothyroidism, which is treated with thyroid hormone; adrenal hyperplasia, which is treated with hormones; and sickle cell disease, in which early treatment with antibiotics helps to prevent hemolytic crises.

Screening for disorders that are not treatable is not generally considered advisable, although some maintain that early diagnosis (for example, of Duchenne muscular dystrophy, or cystic fibrosis) might help parents plan their future reproduction more effectively.

Screening tests are not definitive diagnostic tests. They may present false positive or false negative results, and must therefore by followed up with more specific tests. They are mandatory for certain conditions in many U.S. States, but not in Canada. No informed consent is required, or even "informed refusal" (where the parent is given the opportunity to sign a statement of refusal). A recent Committee report from the United States Institute of Medicine[6] recommends not only that offering screening be mandatory, but that informed consent be an integral part of newborn screening. Some members of the Committee, including the Chairman, consider this recommendation idealistic. Indeed, its implementation might increase the human and economic cost of the program to an unacceptable level.

The tests are often done on blood spots, stored on filter paper, which are often stored, and could be used, retrospectively, for other kinds of DNA testing. This raises some legal and ethical issues.

9. TESTING FOR DISORDERS OF POST-NATAL ONSET

(a) INTRODUCTION

Some deleterious genes do not result in overt disease until well after birth, and perhaps not until late adult life. Some dominant genes will always produce their effect if the person who carries the gene lives long enough. These are said to have complete *penetrance*. There are, however, genes that may express themselves overtly in some carriers of the gene but not others, for reasons that are not well understood. They are said to have *reduced penetrance*. In formal genetics the penetrance of a dominant gene is the percent of carriers that show its effect. Since carrying a gene with reduced penetrance simply increases the probability of the carrier manifesting the disease, such genes can be called *susceptibility* genes. In a sense, penetrance can be thought of as an age-dependent phenomenon. For the penetrance of Huntington disease (discussed below) is fifty percent at age forty-eight (since fifty percent of carriers are affected by this age) and one hundred percent at age eighty.[7] The penetrance of susceptibility genes also increases with age, but never (by definition) reaches one hundred

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[6] Andrews, Fullarton, Holtzman and Motulsky, *Assessing Genetic Risks*[:] *Implications for Health and Social Policy* (1994).

[7] Harper, *Practical Genetic Counselling* (1993).

percent within the normal life span. There is no fundamental difference between genes for late-onset disorders with full penetrance and predisposing genes in terms of the social and ethical issues they raise in the context of genetic testing.

(b) Predictive Testing

Testing for genetic disorders of late onset is called *predictive* or presymptomatic testing, since the presence of a mutant gene, revealed by a DNA test, predicts that the carrier will develop the disease (full penetrance) or has an increased chance to do so (reduced penetrance).

The condition most extensively investigated from this point of view is Huntington disease, a dominant disorder that produces progressive dementia, uncontrollable movements, and eventual death. Overt signs may appear anywhere from the third to the eighth decade.

Before the gene was mapped to chromosome 4, in 1983, the offspring of an affected individual could be counselled only that they had, when they were conceived, a fifty-fifty chance of inheriting the mutant gene. The longer they survive without developing the disorder, the less likely they are to have inherited the gene. For example, fifty percent of gene carriers have developed the disease by age forty-eight, so if the offspring of an affected person is still healthy at age forty-eight, their risk has fallen from fifty percent to thirty-three percent. Insurance companies do not seem to have appreciated, or at least paid attention to, this statistical refinement.

The gene was mapped to chromosome 4, by linkage to certain DNA markers (RFLPs) that were very close to the Huntington locus, and would almost always be transmitted with it. Thus, it became possible to predict whether a near relative of an affected person was or was not a carrier of the gene. If an affected woman (say) carried different forms of a marker closely linked to the Huntington gene on her two chromosome 4s, and received one of those markers from the affected parent (or had an affected sib with the same marker) it follows that that marker was on the same chromosome 4 as the Huntington gene. That marker can then be used to predict whether the woman's children inherited the Huntington gene; if they have the marker they also inherited the Huntington gene—always allowing for the small chance (say two percent) that the disease gene and the marker "change partners" (crossing over). So, instead of a thirty-three percent probability of having inherited the gene, the forty-eight year old offspring has either a two percent or a ninety-eight percent probability. This form of predictive testing requires that several members of the family are available and that two forms of the marker are segregating, that is, that the family is informative.

When the gene was cloned and sequenced it was found that the mutant and non-mutant genes could be distinguished directly with the use of appropriate probes, so the prediction could be made with virtual certainty, and without the need for linkage analysis. An increasing number of mutant genes are becoming recognizable at the DNA level, so predictive testing can be done for more and more conditions with more and more precision.

The advent of predictive testing has raised a number of issues, practical and ethical, that did not exist previously, at least not with the same urgency. The first issue to arise usually

involves a person, let us assume a female, who knows that she is at risk, and becomes aware that there is a predictive test. One experienced geneticist[8] indicates that this is the most difficult counselling situation he ever encounters. To decide whether to have the test involves a choice between living with the uncertainty she now has (and a diminishing risk as she grows older, unaffected), or taking the test and either finding that she is sure to get this devastating disease or being reassured that she will not get it. She may want to have the test so that she can make an informed choice about having children, and be relieved of anxiety if she does not carry the gene, but not want to take a step that may lead to her finding out that she is doomed. Most follow-up studies, incidentally, report that those who take the test consider the long-term result a benefit, whether the answer is yes or no, although in both cases there may be an initial period of stormy emotional adjustment.[9]

The situation is so complex, and so emotionally loaded, that geneticists have approached the problem cautiously. The Canadian Collaborative Study on Predictive Testing has been a leader in developing a protocol, which involves intensive evaluation and counselling before the test, and long-term support and evaluation subsequently.[10] A conflict may arise in situations in which a person who is at risk because of an affected parent chooses not to take the test, but the person's children, or other relatives, want them to, because the results would have immense significance for them. Thus, we have a conflict between one person's right to know and another's right not to know. This problem disappeared in the case of Huntington disease, when direct testing became possible, but remains for other disorders for which predictive testing can be done only with linked markers. In some of these families "exclusion testing" may be a solution; the markers may show either that the child did not inherit the deleterious gene, or that it has the same risk as the at risk parent, without revealing the status of the at risk parent. If the at risk parent becomes affected, however, a child found to have the same risk will then be known to have inherited the deleterious gene. Thus, exclusion testing is also a complex genetic counselling problem.

Predictive testing of children is generally disapproved of, since it transgresses the child's right not to know, and because knowing that a person is destined to develop a serious, or devastating disease may influence adversely the ways in which they are treated by their families, friends, employers, insures or even doctors.[11] An exception would be in the case of disorders that can be prevented, or at least alleviated.

(c) Testing for Susceptibility Genes

There is a rapidly increasing number of disorders in which one or more genes that increase the probability of getting the disorder have been identified at the DNA level, but whether a gene carrier actually gets the disorder depends on environmental factors, which are

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8 *Ibid.*

9 Adam, Wiggins, Whyte, *et al.*, "Five Year Study of Prenatal Testing for Huntington's Disease: Demand, Attitudes, and Psychological Assessment" (1993), 30 J. Med. Genet 549-556.

10 *Ibid.*

11 Clark, "The Genetic Testing of Children" (1994), 31 J. Med. Genet. 785-797.

usually poorly understood, or perhaps, in part, on chance. As noted previously, the issues raised by testing for these disorders do not differ fundamentally from those raised by testing for late-onset disorders with full penetrance. However, the importance of the issues will vary with the penetrance of the gene in question. A gene with low penetrance that doubles the carrier's risk of, say, diabetes to one percent will not attract the attention of insurance companies or be a candidate for screening programs, whereas one with higher penetrance that increases the risk by eight-fold, to eighty percent as for breast cancer, will have much the same impact as one with full penetrance.

10. GENETIC TESTING FOR REPRODUCTIVE STATUS

Genetic testing for reproductive status refers to testing persons, or couples, to determine if they are at increased risk for having a child with a genetic disorder, whether autosomal recessive, X-linked recessive, or autosomal dominant. The possibilities have expanded greatly with the rapid increase in the number of genes identified and eligible for carrier detection by DNA analysis. Testing for reproductive status for autosomal dominant disorders has already been discussed under Predictive Testing.

For recessive disorders, testing for reproductive status may be done on a family basis or by population screening. Testing on a family basis begins from an affected individual, and tests near relatives to identify those who are carriers of the recessive gene and therefore at high risk of having affected offspring if (in the case of autosomal recessive disorders) they mate with other carriers, or (for X-linked recessive disorders) are female. The near relatives of carriers can then be tested, and so on.

Genetic testing for reproductive status at the family level does not seem to evoke legal or ethical issues very often, since the impetus for testing usually comes from the family, although the question of the right not to know or of disputed paternity[12] may arise.

Genetic testing for reproductive status on a population basis (screening) is done only for conditions that are frequent enough in the population to justify the expense, and are treatable. Thus, most genetic screening for carriers is done in special populations in which a particular genetic disorder is unusually frequent, such as Thalassemia in Mediterranean populations, sickle cell anemia in populations of West African descent, and Tay Sachs disease in Ashkenazi Jews. The test must be simple, cheap, and accurate.[13] There has been considerable discussion about population screening for pancreatic cystic fibrosis, which is relatively common in Caucasian populations, but the consensus has been that population screening is not advisable, in view of the genetic heterogeneity of this disorder. Mutations may occur in different parts of the gene. Screening only for the most frequent mutation would miss an appreciable number of carriers (false negatives) leading to a false sense of security, and screening for all known mutations would be expensive and still result in a small number of false negatives. Cystic fibrosis carrier testing on a family basis, starting from known

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[12] Macintyre and Sooman, "Non-paternity and Prenatal Genetic Screening" (1991), 338 Lancet 869-871.

[13] Andrews, Fullarton, Holtzman and Motulsky, *supra,* note 6.

homozygotes, is considered to be more effective.[14] There is also concern that testing may be offered by commercial laboratories, without appropriate regulation, and counselling resources.

Population screening for carrier detection raises some social issues, mostly arising from the fact that most, if not all, such programs are directed towards particular ethnic groups. This may lead to fears of racial discrimination, or even (as in the early sickle cell screening programs) accusations of genocide.[15] Even within the ethnic group, there are concerns about possible stigmatization of carriers. There is much discussion about who should be screened, and when (birth, high-school, marriage, first pregnancy?), and there is a strong consensus that a successful screening program requires thorough consultation with, and education of, the population to be screened. Some of the concerns may lead to what may be considered overreaction. For example, there are some who would require sickle cell screening for *all* members of the population (mostly at low risk) rather than just for those of West African descent, in order to avoid any risk of ethnic stigma. And there are those who would require "fully informed" consent for screening, to an extent that would make the screening program overwhelmingly cumbersome.

11. PRENATAL TESTING FOR GENETIC DISORDERS

(a) TECHNIQUES OF PRENATAL DIAGNOSIS[16]

Prenatal testing for genetic disorders involves obtaining cells from the fetus and examining its chromosomes, DNA, or (to a diminishing extent) enzymes. Prenatal diagnosis by ultrasound involves structural anomalies, mostly with a complex causal basis, and will not be considered in this discussion of genetic testing. Techniques for obtaining fetal cells include amniocentesis, chorionic villus sampling, cordocentesis, fetoscopy, preimplantation diagnosis, and use of fetal cells in the maternal serum.

Amniocentesis involves drawing fluid (with a needle, under ultrasound guidance) from the amniotic cavity, which contains living cells cast off from the fetus that can be extracted and used for genetic testing. The fluid itself can be analyzed for biochemical constituents such as alpha-fetoprotein or hormones, as in the "triple test", which screens for certain severe malformations and chromosome disorders. Risk for maternal complications is negligible, and risk of inducing an abortion is about one in 200. However, amniocentesis is usually done at around the sixteenth week of pregnancy, which means that, when a serious disorder is found and the couple decides on an abortion, it must be done at eighteen to twenty weeks, which is close to the time when termination becomes undesirable for obstetrical reasons. The procedure is increasingly being done at around the twelfth week; results suggest that the risk

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[14] Nance, "Statement of the American Society of Human Genetics on Cystic Fibrosis Carrier Screening" (1992), 51 Am. J.Hum. Genet. 1443-1444.

[15] Andrews, Fullarton, Holtzman and Motulsky, *supra,* note 6.

[16] See, generally, Nora and Fraser, *supra,* note 3.

of inducing an abortion is somewhat higher (approximately four percent), but that this may be justified by the benefits of earlier testing.[17]

Chorionic villus sampling (CVS) involves biopsy of fronds growing from the fetal placenta as they grow out to invade the uterine lining. Genetic testing can be done directly on the tissue, or after culture. The biopsy may be done through the vagina or through the abdominal wall; the latter route is gaining preference. CVS can be done as early as the ninth week of pregnancy, but is usually done around eleven weeks, as there is an increase in the frequency of limb and craniofacial anomalies when testing is done before this (although the actual risk is approximately three per 1,000).[18] Because the placental tissues become separate from those of the embryo early in development, chromosomally abnormal cell lines that arise in the former (resulting in mosaicism) may not exist in the latter. Thus mosaicism found at CVS does not necessarily reflect the status of the embryo, and amniocentesis may be required for clarification. Furthermore, CVS cannot be used for tests on the amniotic fluid. The advantages are that results may be had more rapidly and earlier in the pregnancy than in standard amniocentesis.

Cordocentesis obtains blood from the umbilical cord. It is used occasionally in situations in which fetal blood is needed, for example, for rapid karyotyping when it is getting close to twenty weeks of gestation. *Fetoscopy* involves direct viewing of the embryo through an optical apparatus. It has an appreciable risk of inducing an abortion (about five percent). Results of ultrasound are now so good that fetoscopy is no longer used, except for rare cases in which fetal biopsy is required.

Preimplantation diagnosis (PID) involves genetic testing before the fertilized ovum implants in the uterine lining. In a frequently used technique, ova are obtained by the techniques of in vitro fertilization (IVF), the fertilized ovum is allowed to develop to around the eight cell stage, and two cells are removed for genetic testing, using PCR or FISH. If the genetic abnormality being tested for is found, the embryo is discarded. If the abnormality is not found the embryo may be replaced in the uterus, where it usually succeeds in reorganizing itself, and development proceeds normally.

This technique is not a great success. It requires the stressful and inefficient procedures of IVF, and the tests are still not fully accurate. Most women who would prefer this to regular PND techniques are either totally opposed to abortion and very desirous of having their own child, or have already experienced an abortion for genetic reasons and are not willing to undergo such a stressful experience again. Although it has been available for over five years, a recent survey counted only twenty-three babies born by this procedure world-wide.[19]

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[17] Nicolaides, Brizot, Patel and Snijders, "Comparison of Chorionic Villus Sampling and Amniocentesis for Fetal Karyotyping at 10-13 Weeks' Gestation (1994), 344 Lancet 435-439.

[18] Olney, Khoury, Alo, *et al.*, "Increased Risk for Transverse Digital Deficiency After Chorionic Villus Sampling: Results of the United States Multistate Case-Control Study, 1988-1992 (1995), 51 Teratology 20-29.

[19] Nisker and Gore-Langton, "Pre-implantation Genetic Diagnosis: A Model of Progress and Concern" (1995), 17 J.Soc. Obst. Gynec. 247-261.

Preimplantation diagnosis may also be used before fertilization, on the polar body, which buds off from ovum, and contains the genotype opposite to that of the ovum. This is referred to as *gametic* preimplantation diagnosis. (It is impossible to do genetic testing of the sperm without destroying it.) Gametic preimplantation avoids the moral concern of those who object to the destruction of an embryo even before implantation. However, the results can be ambiguous, and the technique is rarely used.

In spite of the poor prospects for preimplantation diagnosis playing a significant role in prenatal diagnosis, it could conceivably open the way to germ-line gene therapy, and it is not too early to start developing policy relating to the ethics and overall merit of the procedure.[20]

Fetal cells in maternal blood. The blood of pregnant women contains a small number (about one per million) of fetal cells. Various ingenious methods are being developed to enrich the proportion of fetal cells in maternal blood samples to a level that permits genetic testing, by DNA probes or FISH. Clinical trials are in progress to establish sensitivities and specificities.[21] If this approach is shown to be feasible it will revolutionize the field of prenatal diagnosis, since there will be no need for invasive procedures (except for follow-up in ambiguous cases), and the tests can be done early in pregnancy—at least as early as eight weeks. Thus, testing will become much cheaper, and presumably the demand will greatly increase, placing a much greater burden on laboratory and counselling services. No new ethical issues would be raised, but existing ones may well become more urgent. For example, diagnosis of sex for non-medical reasons, and prenatal paternity testing would become easier, so the question of whether stricter control of laboratories providing such services is required becomes an issue for consideration.

(b) Indications for Prenatal Diagnosis

Prenatal diagnosis is normally done for pregnant women whose offspring are known to be at risk for a serious disorder. By far the largest group (eighty percent) are women who have reached an age at which risk of a chromosomal disorder has become high enough to justify the procedure. The "cut-off" age is decided pragmatically, by balancing the chance of finding a positive result against the expense, and stress, of testing a large number of women. Most centres arrive at a cut-off age of thirty-five. The second largest group (six percent) are couples referred because a near relative has had a neural tube defect or from ultrasound or MSAFP screening. A minority (about two percent) are couples where the family history, or results of screening, indicate an increased risk for a serious single-gene disorder.[22]

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[20] Pergament and Bonnicksen, "Preimplantation Genetics: A Case for Prospective Action" (1994), 52 Am. J.Med. Genet. 151-157.

[21] Bianchi, "Clinical Trials and Experience: Boston" (1994), 731 Ann. New York Acad. Sci. 92-102.

[22] Hamerton, Evans and Strunc, "Prenatal Diagnosis in Canada - 1990: A Review of Genetic Centres", in *Current Practices of Prenatal Diagnosis Canada, Research Studies of the Royal Commission on New Reproductive Technologies* (1993) Vol. 13, 1-184.

In Canada, about 25,000 prenatal genetic tests are performed each year, which represents approximately five percent of all pregnant women. In about five percent of those cases, a serious disorder is found. About eighty percent of the couples involved decide on abortion. Genetic abortions in Canada constitute less than one percent of all therapeutic abortions.[23]

As noted above, the usual indication for prenatal diagnosis is an increased risk that a child will be born with a serious disorder. This raises the question of how serious a disorder needs to be in order to justify "therapeutic" abortion. The question is complicated by the fact that abortion can be done for social reasons without any increase in risk for a disorder.

Probably fetal sex is the most troubling condition that presents itself in the context of whether prenatal diagnosis is justified, when the request is made for social, rather than medical reasons. Geneticists, in general, find the idea of doing prenatal diagnosis, with intent to abort a fetus of the unwanted sex, rebarbative. On the other hand, they respect the principle of autonomy, and the directive to be non-directive. The Canadian Guidelines for prenatal diagnosis (1991) states that "[d]etermination of sex for non-medical reasons...is not considered to be appropriate", but they do not forbid it. The Royal Commission on New Reproductive Technologies[24] recommends that such testing, as well as prenatal diagnosis for susceptibility genes, should be prohibited; although it allows prenatal diagnosis for late-onset disorders, provided there is extensive pre- and post-test counselling.

In fact, in Canada, there are few requests for prenatal diagnosis of sex for non-medical reasons, and referred couples almost all decide against termination, after counselling.[25] The issue becomes even more acute in cases in which there is a legitimate indication (usually maternal age) for prenatal diagnosis and the couple indicates (or there is a suspicion) that they will terminate the pregnancy of a fetus of the unwanted sex.

Prenatal diagnosis for paternity testing also raises some difficult ethical issues, in which reluctance to abort a healthy fetus conflicts with the possible destruction of a marriage if the fetus has the "wrong" father. The Board of the Canadian College of Medical Geneticists has stated that "[i]n most circumstances prenatal diagnosis for paternity testing is not a medically indicated test". In the minority, the decision presumably becomes a matter of judgment and negotiation.

In the case of prenatal diagnosis for diseases of late-onset the question of how severe a disease must be to justify abortion as a "preventive" measure is extended to diseases that may not appear until middle-age or later. Geneticists may not see such disorders as having a sufficient degree of severity but those who have had direct, and often tragic, experience with the disorder may think otherwise. There is a consensus that, if prenatal diagnosis is done there

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23 Canada, Royal Commission on New Reproductive Technologies, *Proceed with Care* (1993) Vol. 2.

24 *Ibid.*

25 *Ibid.*

should be a commitment to abort. If not, there is no reason to do the test prenatally, and there are serious problems with predictive testing in children, as mentioned previously.[26]

12. GENETIC TESTING FOR NON-MEDICAL PURPOSES

Genetic testing for non-medical purposes is done to define individuality and to establish relationships by the use of normal genetic variants, or polymorphisms. A polymorphism is a genetic difference that is common enough in the population to be useful for these purposes (arbitrarily set at one percent). Polymorphisms such as blood-groups and HLA types (white cell blood groups) have been used for these purposes for many years. The existence of large numbers and great variability of DNA markers such as RFLPs, VNTRs and SSRs has greatly increased the scope and power of this approach.

(a) Genetic Testing to Establish Individuality

This application of DNA testing makes use of the fact that there are many polymorphic genes, often with many forms of the same gene, that are constantly being shuffled and recombined in the population. It follows that, if one tests enough loci, the possibility that two individuals (other than identical twins) will be identical at all of them is infinitesimal. Thus, a specimen of a person's DNA, from blood, hair, skin, semen or other tissue, when analyzed by an adequate number of probes for DNA markers, by reliable techniques, provides that person with a unique individuality just as specific as that of traditional finger prints. Hence the term "DNA fingerprinting". The odds against two unrelated individuals having the same DNA "fingerprint" are overwhelming.

This use of genetic testing is most widely recognized in the forensic context, where the DNA of a suspect is compared with that of a specimen of blood or other tissue found at the scene of a crime. If the DNA markers differ in the suspect individual and the specimen, the suspect cannot be the source of the tissue. If they correspond, the chance that the tissue belongs to anyone else is remote.

Other uses of DNA testing to establish individuality include the banking of DNA for future identification of persons accused, or convicted, of violent crimes, or of soldiers, or of newborn infants. This raises issues of autonomy and confidentiality.

(b) DNA Testing to Establish Relationships

Every person has two of every kind of gene, one inherited from the mother and one from the father. This person gives either their maternal or paternal form of the gene to each child, and so does the other parent. If the gene is a DNA marker it is polymorphic and, ideally, it would be possible to identify all six of the three pairs of genes at a particular locus in a parent-child unit. This can be used to establish relationships in a number of ways.

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[26] Bloch and Hayden, "Opinion: Predictive Testing for Huntington Disease in Childhood: Challenges and Implications" (1990), 46 Am. J.Hum. Genet. 1-4.

If the child possesses a DNA marker not present in either putative parent, then one of them (usually the father, hence the name "paternity testing") is not the biological parent, barring the remote chance of a mutation. Thus, assuming that an adequate number of markers are tested with reliable techniques, if a putative father is not the real father, DNA testing is virtually certain to reveal it . If no incompatibility is found, the question becomes what the probability is that another individual could possess the same array of DNA markers as that contributed to the child by the putative father. As in the forensic situation, this probability becomes more and more remote as the number of DNA markers analyzed is increased.

A similar reasoning can be used to confirm parental relationships, for example, by immigration authorities. Siblings, or nephews and nieces, should be much more similar in their DNA polymorphisms than unrelated individuals, so their array of markers should confirm, or deny, a claimed relationship.

(c) Genetic Testing for Population Studies

DNA polymorphisms may also be used for research in population genetics in various ways. For example, they may be used to trace the historical origins of populations. In groups that have separated earlier in their evolutionary history there will be more differences in their polymorphisms.

Similarly, the histories of particular genes can be traced by studying their association with closely linked polymorphisms in various populations and, for this, the frequencies of the polymorphisms must be known.

13. CONCLUSION

Genetic testing is playing an increasingly large part in our lives—in neonatal screening, carrier screening, prenatal diagnosis, predictive testing for early and late-onset disorders with full penetrance, for predisposing genes, for forensic purposes, by immigration authorities, employers, and insurers. It is predicted that every disorder known to be associated with a single gene difference will be mapped within the next five years.[27] Thus, the number of disorders for which genetic testing can be done is increasingly apace.

It follows that opportunities for abuse and exploitation of these techniques are also increasing. Our challenge will be to protect people from the dangers of unwise or unscrupulous application of genetic testing, without obstructing their beneficent applications towards our welfare.

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[27] Collins and Galas, *supra,* note 1.

CHAPTER 3

HUMAN RIGHTS AND THE GENE

1. INTRODUCTION

In order to understand the current "climate" surrounding genetic testing generally, the larger political debate on the human genome as such is instructive. While often confined to the issues of the direction of human genome research, the different international approaches are indicative of an understanding of its far-reaching implications. This is because genetic material and its information is both universal and individual, the DNA of the human person being in the stream of living matter, but also unique to each person. At the level of the gene pool of the human species, human genetics is ignorant of politics and social boundaries since the human genome map is not only anonymous, but demonstrates membership in the human species irrespective of race or colour. Indeed, due to our common, universal ancestry, the information gleaned from human genome mapping will apply to everyone irrespective of individual differences.[1]

These factors make the human genome mapping project and possible limitations to prevent abuse particularly amenable to future protection under the international law concept of the common heritage of mankind.[2] This concept stems from the need for preventing ownership of things of communal interest and for preserving things that are of international interest. Its first recognition was in relation to the sea, which was considered *res communis,* so that nations with shorelines had rights of servitude only to their own territorial waters. Like the legal concept of a trust under private law (once limited to "things" (*res*) and now extended to interest and rights), the concept is akin to that of a "public" trust, which serves to assist in the transmission of property or interests from one generation to the other. The basic common factors of the common heritage approach are that: utilization must be peaceful;

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1 B.M. Knoppers & C.M. Laberge, "Social Geography of Human Genome Mapping" in Z. Bankowski & A.M. Capron, eds, *Genetics, Ethics and Human Values: Human Genome Mapping, Genetic Screening and Gene Therapy*, (Geneva: Council for International Organizations of Medical Sciences, 1991) 39-55; B.M. Knoppers, "Le Genome humain: un patrimoine universel, personnel et communautaire" in M.J. Melançon & R.D. Lambert, *Le Genome Humain: Une repsonsabilité scienifique et sociale* (Québec: Presses de l'Université Laval, 1992) 101-111.

2 See generally the study paper prepared for the Law Reform Commission of Canada from which this part is extracted in B.M. Knoppers, *Human Dignity and Genetic Heritage* (Ottawa: Law Reform Commission of Canada, 1991) at 18-22; K. De Jager, "Claims to Cultural Property under International Law" (1988) 1 Leiden J. Int'l L. 183; Alexandre-Charles Kiss, "La notion de patrimoine commun de l'humanité" (1982) II, RCADI 99; *Revised Outline of a Declaration on the Protection of the Human Genome*, International Bioethics Commitee of UNESCO, (Paris: March 7 1995) Report of H. Exc. Mr. Hector Gros Espiell, President of the Legal Commission of the IBC, at 51.

access must be open to those who have a right, while respecting the rights of others (therefore, responsibility for abuse); sharing must be equal, and, due to its indivisible character, the patrimony must be administered in the interest of all the common welfare.

On an international level, this approach, when combined with that of personal control under private law, may offer both the necessary protection of the genetic patrimony of mankind and yet respect individual freedom and privacy. Such an approach would parallel the actual biological reunion of the individual pattern and gene pool source found in the human person. It would provide for individual control and yet encourage the individual, in certain instances, to relinquish some control over his cells or the information they contain to the public domain or according to the needs of other family members. It would also set the international, ethical, and legal framework for legitimate uses and guard against abuses. There have been both regional[3] and international appeals[4] for the legal protection of the human genetic patrimony on the basis of respect for the inherent dignity of the human person. In 1994, the International Bioethics Committee of UNESCO began work on a *Preliminary Outline of a Declaration on the Protection of the Human Genome* for 1998. Initially seeking to proclaim the human genome as "the common heritage of the human species", the *Revised Outline* of this Declaration proposes that the "human genome is the common heritage of humanity".[5] This chapter will first examine the legal protection offered by international and national human rights law, and will then consider a more contemporary and specific source of normative obligations, medical ethics.

2. HUMAN RIGHTS LAW

Human rights law is distinct from general legal theory and practice. The human rights and fundamental freedoms found under international codes ascribe the three particular

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3 *European Convention for the Protection of Human Rights and Fundamental Freedoms*, November 4 1950, 213 U.N.T.S. 221, E.T.S. No. 5 (hereinafter *European Convention*). More recently and more specifically see: Council of Europe, *Draft Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*, (Strasbourg, July 1994) as amended in February 1995 (Council of Europe, P.A. First part of its session (January 30-February 3) on the draft Bioethics Convention, *Adopted*, Opinion No. 184 on the Draft Bioethics Convention) (hereinafter Council of Europe, *Draft Bioethics Convention*). See *infra*, note 24 and accompanying text.

4 The organization "Universal Movement for Scientific Responsibility" is seeking an amendment of the Universal Declaration of Rights. See J. Dausset, "Éditorial: Les droits de l'Homme face au progrès des connaissances" (1989) 17 Sciences et devenir de l'homme, Cahiers du M.U.R.S. at 3-11; See *infra*, this ch., sec. 3. The Valencia Declaration on Ethics and the Human Genome Project, II Workshop on International Cooperation for the Human Genome Project, Spain, November 14 1990, in (1991) 42(2) Intern'l Digest of Health Legis. 338-339 (hereinafter *Valencia Declaration*), recognised the responsibility of scientists to ensure that genetic information be used only to enhance human dignity.

5 United Nations Educational, Scientific and Cultural Organization, International Bioethics Committee, Second Session, *Preliminary Outline of a Declaration on the Protection of the Human Genome* (Paris, 1994) (hereinafter UNESCO, *Preliminary Outline of a Declaration*); and the *Revised Outline of a Declaration on the Protection of the Human Genome*, International Bioethics Commitee of UNESCO, (Paris: March 7 1995). The human genome, as a fumdamental component of the common heritage of humanity, needs to be protected in order to safeguard the integrity of the human species, as a value in itself, and the dignity of each of its members.

characteristics of inherence, inalienability, and equality as the features that distinguish human rights from other legal rights. This means that every person is born vested with these rights, cannot sell or purchase them, and should be treated with equal dignity and respect as to these fundamental rights and freedoms because every person is so "different from each other as to be unique".[6]

Another interesting feature of human rights law is that, while under other legal theory and practice mutual rights and duties arise from mutuality of interests, the protection and promotion of human rights fall on the state, which ultimately must impose those same constraints upon itself through the mechanism of enforcement by the international community.[7] Furthermore, respect for these basic human rights and freedoms goes beyond mere prevention or protection from interference or intrusion to creating positive obligations on the state.[8] It should also be noted that while there may be "reasonable"[9] limitations on the exercise of human rights, or even restrictions or derogations in times of emergencies, attempts to classify or distinguish by means of a ranking have little practical utility.[10] Finally, the bias of what may be termed as the "international code of human rights law" in force today is one in favour of the kind of society that displays a specific coherent set of values: [11]

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6 P. Sieghart, *The Lawful Rights of Mankind* (New York: Oxford University Press, 1986) at 42; L.C. Green, "Institutional Protection of Human Rights" (1987) 28 C. de D. 547 (summarises the history of human rights protection); Eugene B. Brody, *Biomedical Technology and Human Rights* (Great Britain: UNESCO, 1993); D. Turp & G. Beaudouin, éd., *Perspectives canadiennes et européennes des droits de la personne* (Montréal: Les Éditions Yvon Blais Inc., 1986); Commission nationale consultative des droits de l'homme, *Les droits de l'homme en question* (Livre blanc) (Paris: Documentation française, 1989); G. Braibant & G. Marcou, éd., *Les droits de l'homme: universalité et renouveau 1789-1989* (Paris: l'Harmattan, 1990). See also M.S. McDougal et al., *Human Rights and World Public Order: The Basic Policies of an International Law of Human Dignity* (New Haven: Yale University Press, 1980) at 461:

> The traditional philosophical justification for protecting fundamental freedom of choice has been in terms of common humanity, of protecting man as man. The basic thrust of the position is that every individual should be treated as an end in himself, not as an instrument for others. It may be conceded that the image that man has developed of himself as being different from animals and other forms of life has had important and beneficent historical impacts upon acceptance and cultivation of all the values we cherish as those of human dignity. More contemporary justifications toward the same ends may, however, be grounded in the modern psychology, which stress the overriding importance to the individual, and to community process, of affording to every individual opportunities for the participations necessary to the development of a constructive 'self', capable of respecting the self and others and therefore of sharing freedom in choice.

7 Sieghart, *ibid.* at 43. See also A. Brudner, "The Domestic Enforcement of International Covenants on Human Rights: A Theoretical Framework" (1985) 35 U.T.L.J. 219-254.

8 P. Leuprecht, "Intervention at the European Parliament Hearing" in Council of Europe, P.A., *Genetic Engineering: Risks and Chances for Human Rights* (Strasbourg: Council of Europe, 1981) at 115; A.M. Connelly, "Problems of Interpretation of Article 8 of the European Convention of Human Rights" (1986) 35 I.C.L.Q. 567 at 573.

9 See, for example, the *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B of the *Canada Act 1982* (U.K.), 1982, c. 11 (hereinafter the *Charter*), s. 1. In international law, only the freedoms from torture and from slavery are absolute rights that may not be restricted.

10 P. Sieghart, *The International Laws of Human Rights* (Oxford: Clarendon Press, 1983) at 127.

11 Sieghart, *supra*, note 6, at 42.

tolerance of diversity; plurality of belief, ideas, and culture; reasonableness and rationality; the peaceable resolution of conflicts under the rule of law; and, above all, respect for the dignity, autonomy, and integrity of every one of its single members.

The respect of these values underlies human rights. Indeed, the recognition of the inherent dignity of the human person is both the source and the framework for human rights law.[12] In the field of human genetics respect for the inherent dignity of the person is paramount. Furthermore, human genetics is intimately linked to a number of human rights, enhanced by international and national instruments, such as: the right to enjoy the benefits of scientific progress; the right to the highest attainable standard of health; the right to life, liberty and security; the right to privacy and family life; the right to marry and to found a family; and, the right to be free from discrimination and to equal treatment. Each of these issues are discussed, in turn, below.

(a) INHERENT DIGNITY OF THE HUMAN PERSON

In 1948, the *Universal Declaration of Human Rights* proclaimed the recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family as "the foundation of freedom, justice and peace in the world".[13] Article 1 of that text acclaims that "all human beings are born free and equal in dignity and rights". Similarly, the *International Covenant on Economic, Social and Cultural Rights* of 1966 states in its preamble that all human rights "derive from the inherent dignity of the human person".[14] Although these provisions have not been authoritatively interpreted or applied by competent, independent, international institutions as being distinct from other human rights,[15] so fundamental is its nature that it can be said that all human rights derive from this inherent dignity.[16]

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12 McDougal et al., *supra*, note 6, Part II c. 5; O. Schachter, "Human Dignity as a Normative Concept" (1982) 77 Am. J. Int'l. L. 848; Knoppers, *supra*, note 2.

13 GA Res. 217/A, 3 U.N. GAOR Pt. 1, UN Doc. A/810 (1948)(preamble) (hereinafter *Universal Declaration*).

14 (1976) 993 U.N.T.S. 3; See also: the preamble to the 1966 *International Covenant on Civil and Political Rights* (1976) 999 U.N.T.S. 171; and at a regional level see: *American Convention on Human Rights* (1969), as reproduced in Inter-American Commission on Human Rights, Organisation of American States, *Handbook of Existing Rules Pertaining to Human Rights* (March 29 1979) O.A.S./ser.L/V/II.23/doc.21rev.6., (hereinafter *American Convention*), Art. 11(1): "Everyone has the right to have his honour respected and his dignity recognised"; *African Charter on Human and Peoples' Rights* (1981) as reproduced in 4 E.H.R.R. 417, Art. 5: "Every human being shall have the right to the respect of the dignity inherent in a human being." Also recognised in the *European Convention*, *supra*, note 3.

15 Sieghart, *supra*, note 10, 309.

16 Knoppers, *supra*, note 2, 23-24: Schacter, *supra*, note 12, at 853-854; See also an interesting Swiss Report: Commission d'experts pour la génétique humaine et la médecine de la reproduction, *Rapport au Département fédéral de l'intérieur et au Département fédéral de justice et police*, (Berne, 1988) in (1992) 43 (4) IDHL at 48: "Le respect de la dignité humaine est la justification suprême de l'ordre juridique. Il trouve son reflet dans les droits fondamentaux définis par la constitution, dans les principes non écrits de l'État fondé sur le droit, ainsi que dans le droit positif."

The right to human dignity was first related specifically to the context of human genetics by the Parliamentary Assembly of the Council of Europe in a 1982 recommendation on genetic engineering.[17] According to that recommendation, "the rights to life and to human dignity protected by Articles 2 and 3 of the European Convention on Human Rights imply the right to inherit a genetic pattern which has not been artificially changed".[18] The Parliamentary Assembly also requested that this right be made explicit in the context of the European Convention on Human Rights.[19] This right to inherit a genetic pattern that has not been artificially interfered with, was again reiterated in certain recommendations of the Parliamentary Assembly of the Council of Europe in 1986[20] and in 1989.[21] No other recognized regional or international governmental body has taken up this appeal for the explicit legal recognition of what could be termed "inalterable genetic rights".[22] The Committee of Ministers of the Council of Europe, in their 1990 recommendation on medical research on human beings, reaffirmed, however, that "medical research should never be carried out contrary to human dignity".[23] The text is general in scope and thus research in human genetics is not identified specifically. It should also be noted that the therapeutic applications of human genetics have always been excluded from the ambit of these tests.

More recently, the Council of Europe Steering Committee on Bioethics has drafted the Draft Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine.[24] It recognizes, in its preamble, the

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17 Council of Europe, P.A., 33rd Sess., Pt III, Texts Adopted, Recommendation 934 (1982) on Genetic Engineering, (hereinafter Recommendation 934 (1982)), s. 4(i).

18 *Ibid.*, Art. 4(i).

19 *Ibid.*, art. 4(ii): "This right should be made explicit in the context of the European Convention on Human Rights"; Art. 7(b) further recommends that the Committee of Ministers, "provide for explicit recognition in the Convention on Human Rights of the right to a genetic inheritance which has not been artificially interfered with, except in accordance with certain principles which are recognised as being fully compatible with respect for human rights (as, for example, in the field of therapeutic applications)".

20 Council of Europe, P.A., 38th Sess., Pt II, Texts Adopted, Recommendation 1046 (1986) on the Use of Human Embryos and Foetuses for Diagnostic, Therapeutic, Scientific, Industrial and Commercial Purposes, sec. 1: "Recalling its Recommendation 934 (1982) on genetic engineering, proposing a range of measures including in particular the recognition of the right to a genetic inheritance which should not be artificially interfered with except for therapeutic purposes".

21 Council of Europe, P.A., 40th Sess., *Texts Adopted, Recommendation 1100 (1989) on the Use of Human Embryos and Foetuses in Scientific Research*, sec. 2: "Noting the contents of the Council of Europe's Parliamentary Assembly Recommendation 934 (1982) and its proposals for the application of genetic engineering on the basis of respect for the genetic heritage of mankind, which shall not be interfered with in individuals save for clearly and scientifically demonstrated preventive or therapeutic purposes".

22 For an analysis of "genetic rights" see Knoppers, *supra*, note 2, 23-31, more precisely at 30: "In the international context, we have seen the dangers of the interpretation of human dignity that concerns the "rights" to an unaltered genetic heritage. Under the guise of protection, such an interpretation would lead to the screening and selection of those individuals suitable to reproduce and, ultimately, to lawsuits within families and between generations." See however, Dausset, *supra*, note 4.

23 Council of Europe, Committee of Ministers, 433rd Meeting, Recommendation No. (90)3 of the Committee of Ministers to Member States Concerning Medical Research on Human Beings, preamble (hereinafter Council of Europe, Recommendation No. (90)3).

24 *Supra*, note 3.

"importance of ensuring the dignity of the human being" and it is "conscious that the misuse of biology and medicine may lead to acts endangering human dignity". Furthermore, respect for human dignity constitutes the cornerstone of this Convention as its purpose and object is to ensure that: "[p]arties to the Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine".[25] Likewise, the International Bioethics Committee of UNESCO affirms, in its Preliminary Outline of a Declaration on the Protection of the Human Genome, that "the aim of the protection of the human genome is to safeguard the integrity of the human species as a value in itself, as well as the dignity of each member of the human family".[26]

At the national level, most constitutions refer similarly to this inherent dignity in either a preambular or substantive context. In Canada, the *Canadian Charter of Rights and Freedoms* [27] does not explicitly refer to the notion of human dignity. However, the notion of human dignity remains a fundamental theme underlying its provisions and its importance has been recognized in numerous cases.[28] The Supreme Court of Canada has referred to human dignity as one of the basic principles and values enshrined in the *Charter*, in stating as follows: [29]

> The Court must be guided by the values and principles essential to a free and democratic society which...embody...respect for the inherent dignity of the human person, commitment to social justice and equality, accommodation of a wide variety of beliefs, respect for cultural and group identity, and faith in social and political institutions which enhance the participation of individuals and groups in society.

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25 *Ibid.*, Article 1.

26 *Supra*, note 5, article 2. Note that the wording of the *Revised Outline of a Declaration on the Protection of the Human Genome* remains virtually the same.

27 *Supra,* note 9. It should be noted that the Charter applies only where government action is involved: *RWDSU* v. *Dolphin Delivery* (1986), 33 D.L.R. (4th) 174 (S.C.C.). In the genetics-health care context, the issue of Charter application can be quite complex since decisions are often made by administrative decision makers such as hospitals or regional health boards rather than by the legislative or executive branches of government. Where, of course, decisions are made directly by government, then the Charter clearly applies.

28 See, for example, *Re B.C. Motor Vehicle Act,* [1985] 2 S.C.R. 486, in which Lamer J. states, at page 512, that: "[s]ections 8 to 14 address specific deprivations of the "right" to life, liberty and security of the person in breach of the principles of fundamental justice, and as such violations of s. 7. They are therefore illustrative of the meaning, in criminal or penal law, of "principles of fundamental justice"; they represent principles which have been recognised by the common law, the international conventions and by the very fact of entrenchment in the *Charter*, as essential elements of a system for the administration of justice which is founded upon the belief on the dignity and worth of the human person and the rule of law." See also *R.* v. *Oakes*, [1986] 1 S.C.R. 103; *R.* v. *Morgentaler*, [1988] 1 S.C.R. 30; *Andrews* v. *Law Society of British Columbia*, [1989] 1 S.C.R. 143; *Kindler* v. *Canada (Minister of Justice)* [1991] 2 S.C.R. 779, Justice Cory dissenting although not on this issue; *Rodriguez* v. *B.C. (A.G.)*, [1993] 3 S.C.R. 519-632.

29 *R. v. Oakes*, *ibid.*, at 136 (Dickson C.J.).

The importance of human dignity in understanding the protections afforded by the *Charter* was further emphasized in *R.* v. *Morgentaler* by Madam Justice Wilson, who wrote:[30]

> The idea of human dignity finds expression in almost every right and freedom guaranteed in the *Charter*. Individuals are afforded the right to choose their own religion and their own philosophy of life, the right to choose with whom they will associate and how they will express themselves, the right to choose where they will live and what occupation they will pursue.

The fundamental nature of this inherent dignity is nowhere more intimately linked to the person than in the relationship of the person to his body and to decision-making in that regard. Two fairly recent cases, one in the United States and one in Canada, have specifically linked the interest of a person in his genetic material to respect for the dignity of that person.

In the 1988 California case of *Moore* v. *Regent of the University of California,*[31] the plaintiff's cells had been used in scientific research and profitable commercial exploitation by his physician without his knowledge. The California Court of Appeal stated: "[f]or better or worse, we have irretrievably entered an age that requires examination of our understanding of the legal rights and relationships in the human body and the human cell".[32] The Court considered one's genetic material to be "far more profoundly the essence of one's uniqueness than a name or face".[33] It held that a "patient must have the ultimate power to control what becomes of his or her tissues. To hold otherwise would open the door to a massive invasion of human privacy and dignity in the name of medical progress."[34] The court considered the plaintiff's cells and genes as "part of his person".[35]

In the Supreme Court of Canada case *R.* v. *Dyment,*[36] a physician collected a blood sample, for medical purposes, from an unconscious patient in the emergency department without his consent or knowledge. The physician handed the blood sample over to the police officer without there being any legal requirement to do so. Analysis of the blood sample was then used to secure the prosecution of impaired driving. The Supreme Court of Canada held

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30 *Supra*, note 28, 166 (Wilson J.).

31 [1988] 249 Cal. Rptr. 494 (Cal. App.2 Dist.); However, the decision of the California Court of Appeal, which recognised a property claim, was dismissed by the Supreme Court of California, *Moore* v. *Regents of University of California*, [1990] 271 Cal Rptr. 146-190. The Supreme Court of California recognized the plaintiff's claim on the basis of breach of fiduciary duty and negligence in failing to obtain adequately informed consent. See *infra*, ch. 4.

32 *Ibid.*, at 504.

33 *Ibid.*, at 508.

34 *Ibid.*

35 *Ibid.*

36 [1988] 2 S.C.R. 417.

that the "use of a person's body without his consent to obtain information about him, invades an area of privacy essential to the maintenance of his human dignity".[37]

In considering the growing potential of genetic technologies and their possible applications in fields such as medicine, forensic science, paternity testing, insurance, or employment, the need for protection of human dignity becomes paramount. The potential legal creation of "genetic rights"[38] in the name of respect for the inherent dignity of the human person, however, raises very troublesome issues with regard to other existing basic rights, such as the right to one's liberty. The possible social ramifications of the violation of "genetic rights" under private law, particularly in the family context, would be without precedent.[39] Moreover, the autonomy to make decisions with respect to procreation, free from governmental interference, has long been a protected right.[40] Respect for human dignity then, may well be realized more effectively in ways other than by asserting claims of right.[41] Social processes, such as education, material benefits or political leadership, or the elaboration of codes of conduct may be more appropriate and effective.[42] Nevertheless, considering the potential of the new genetics, a more explicit protection of the basic dignity of the human person is of utmost importance, due to the freedom traditionally accorded to scientific endeavour.[43]

(b) RIGHT TO ENJOY THE BENEFITS OF SCIENTIFIC PROGRESS

The 1948 *Universal Declaration of Human Rights* acclaimed the right of everyone "freely...to share in scientific advancement and its benefits".[44] The *International Covenant on Economic, Social and Cultural Rights*, which came into force in 1976, more specifically recognizes the right of everyone "to enjoy the benefits of scientific progress and its applications".[45] Moreover, the States Parties to that Covenant undertake "to respect the freedom indispensable for scientific research and creative activity".[46] It seems, however, that these provisions "only require states not to *prevent*" scientific progress and do not in fact

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37 *Ibid.*, at 431-432.

38 For an overview and a critique of "genetic rights" see Knoppers, *supra*, note 2, at 25-31.

39 Parents have traditionally been protected from legal claims by their children as to quality of life choices under the doctrine of intrafamilial tort immunity under private law. See *infra*, ch. 8.

40 See *infra*, this ch., sec. 2(f).

41 Schacter, *supra*, note 12, at 853.

42 *Ibid.*; See *infra*, this ch. sec. 3.

43 See the *Declaration of Inuyama*, in Z. Bankowski & A.M. Capron, eds, *Genetics, Ethics and Human Values: Human Genome Mapping, Genetic Screening and Gene Therapy*, (Geneva: Council for International Organizations of Medical Science, 1991); Council of Europe, *Draft Bioethics Convention*, *supra*, note 3; UNESCO, *Preliminary Outline of a Declaration*, *supra*, note 5.

44 *Supra*, note 13, Article 27.

45 International Covenant on Economic, Social and Cultural Rights, supra, note 14, art. 15(b).

46 *Ibid.*, Article 3. The more recent Council of Europe, *Draft Bioethics Convention*, *supra*, note 3, Article 14, also provides for the freedom of scientific research.

create any state obligations.[47] According to the Ontario Law Reform Commission's *Report on Human Artificial Reproduction and Related Matters,*[48] the various provisions of the *International Covenant on Economic, Social and Cultural Rights,*[49] taken together, "may require ratifying States to protect the establishment of families, by legislation if possible and necessary, and to afford individuals access to such 'benefits of scientific progress and its applications'...or at least not to deny that access where it is available".[50] Moreover, "any legislation resulting from a recommendation to control scientific research will be subject to rigorous scrutiny under the [Canadian] Charter if it contains provisions that appear to restrict, for instance, the liberty of researchers or the liberty and security of others to enjoy the benefits of research achievements".[51]

Scientific research is necessary for the advancement of humanity, but the science of human genetics works with the very material of which we are made—our human genetic material and its highly personal information.[52] For this reason, certain European countries have prohibited or limited by law, certain types of research on the human embryo in the context of the new reproductive technologies,[53] but the mapping of the human genome as such has not been legally prohibited. Nevertheless, some of its applications are attracting legal attention. While somatic cell alteration has gradually become accepted as the equivalent of traditional surgical or medical intervention,[54] germ line therapy, which would involve

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47 Sieghart, *supra*, note 6, at 145.

48 Vols. 1&2 (Toronto: Ministry of the Attorney General, 1985).

49 See Articles 2(1), 10(1), 15(1)b) and 15(3) of the International Covenant on Economic, Social and Cultural Rights, supra, note 14.

50 Ontario Law Reform Commission, *supra*, note 48, at 37.

51 R. Cook, "New Reproductive Technologies: International Legal Issues and Instruments" Royal Commission on New Reproductive Technologies, *Overview of Legal Issues in New Reproductive Technologies* Research Studies; no. 3 (Ottawa: Supply & Services Canada, 1993) 659-673, 668.

52 See *supra*, ch. 1..

53 For an overview of legislation and policies around the world on human genetics see: B.M. Knoppers & R. Chadwick, "The Human Genome Project: Under an International Microscope" (30 September 1994) 265 Science 2033-2034; For the impact of such legislation on some aspects of new reproductive technologies see especially: B.M. Knoppers, S. LeBris, "Recent Advances in Medically Assisted Conception: Legal, Ethical and Social Issues" (1991) 17(4) Am J Law & Med 330-361; B.M. Knoppers, S. LeBris, "Reproductive Genetics: Canadian and European Perspectives" (1993) 8 Suppl. 1 Fetal Diagn Ther 189-201 (hereinafter Knoppers & LeBris 1993a); B.M. Knoppers, S. LeBris, "Ethical and Legal Concerns: Reproductive Technologies 1990-1993" (1993) 5 Current Opinion in Obstetrics and Gynaecology 630-635 (hereinafter Knoppers & LeBris 1993b).

54 For an overview see Knoppers & Chadwick, *ibid.*; See also: *Recommendation 934 (1982)*, *supra,* note 17, section 4ii): "[T]he explicit recognition of this right [right to inherit a genetic pattern that has not been artificially changed] must not impede development of the therapeutic applications of genetic engineering (gene therapy) which holds great promise for the treatment and eradication of certain diseases which are genetically transmitted". See also Council of Europe, *Draft Bioethics Convention*, *supra*, note 3, section 16; World Health Organization, *Hereditary Diseases*, WHO Technical Report Series (Geneva: 1995) (forthcoming) at 12, which provides that somatic gene therapy does not appear to require a special set of regulations but does need to be brought clearly into the normal system of licensing of medicines, and approval by ethics committees which govern the introduction of new clinical products; D.C. Wertz et al., *Guidelines on Ethical Issues in Medical Genetics and the Provision of Genetic Services*, (Geneva: World

permanent alteration of the cell line and affect one's progeny, has not been accepted.[55] Certain countries have published reports or guidelines[56] and others adopted laws[57] in which genetic therapy that would affect future generations is prohibited on the basis of the relationship between respect for human dignity and the inheritance of an unaltered genetic patrimony.

Due to the very individual and yet ultimately, global nature of the mapping endeavour, it is certain that any allocation of public moneys for research in human genetics cannot be free from public scrutiny. Furthermore, as the public becomes more informed, claims could

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Health Organization, 1995) (forthcoming); the Norwegian Act: *The Act Relating to the Application of Biotechnology in Medicine* (June 1994), in (1994) June-July Bull. Med. Eth., 8-11, (hereinafter Norway: *Act Relating to the Application of Biotechnology in Medicine*) and more recently Law No. 56 of August 5 1994 on the medical use of Biotechnology, in (1995) 46 Intern'l Digest of Health Legis. 51; section 7.1 "Conditions for gene therapy: The human genome may only be altered by means of somatic gene therapy for the purpose of treating or preventing serious disease from occurring." Despite a widening consensus, however, this area remains open to questioning. See R. Munson, L.H. Davies, "Germ-Line Gene Therapy and the Medical Imperative" (1992) 2:2 Kennedy Institute of Ethics Journal 137-158.

55 See: D.C. Wertz, *ibid.* at 72; the International Workshop on Legal Aspects of the Human Genome Project, "*Bilbao Declaration*", Bilboa, May 24-26 1993, in (1994) 45:2 Intern'l Digest Health Legis. 338-339; Council of Europe, *Draft Bioethics Convention*, *supra,* note 3, section 16 which, as amended (February 1995), reads: "An intervention on the human genome may only be undertaken for preventive, therapeutic or diagnostic purposes without any intervention in the germ cell line"; European Community, Council Decision 94 913 EC of December 15 1994 adopting a specific Programme of Research and Technological Developments, Including Demonstration, in the Field of Biomedicine and Health, in (1995) 46 Intern'l Digest Health Legis. 163 at 164; European Commission, "Group of Advisers on the Ethical Implications of Gene Therapy" (1995) 46 Intern'l Digest Health Legis 271 article 2.7, especially the "Symposium: Regulating Germ-line Gene Therapy" (1994) 13:2 Special Issue of Politics and the Life Sciences; Knoppers, *supra*, note 2 at 28. However, from a medical ethics point of view, the need for further discussion is considered essential in *The Declaration of Inuyama*, *supra*, note 43; See also *Valencia Declaration,* Principle 8, *supra*, note 4.

56 See, for example, Medical Research Council of Canada, *Guidelines for Research on Somatic Cell Gene Therapy in Humans*, Minister of Supply & Services Canada, Ottawa, 1990 at 41; Royal Commission on New Reproductive Technologies, *Proceed with Care: Final Report of the Commission on New Reproductive Technologies*, Minister of Government Services Canada, Ottawa, 1993 rec. 241, 269 & 270; *Health Canada*, Government of Canada, Minister of Health, Diane Marleau, July 27 1995 Communiqué proposing a voluntary moratorium , Committee of the Health Council of the Netherlands, *Heredity: Science and Society*, The Hague, 1989; Committee on the Ethics of Gene Therapy, *Report presented to Parliament by Command of Her Majesty* (London: 1992) rec. 5.11, 5.2 & 7.2.

57 For an overview of legislation or proposed legislation, see Knoppers & Chadwick, *supra*, note 53; More specifically see: Austria: *Reproductive Medicine Law*, (June 4 1992), in (1993) 44:2 Intern'l Digest of Health Legis. 247-248 and more recently "The Gene Technology Law" (1995) 46 Intern'l Digest of Health Legis 42; Germany: *Embryo Protection Law (October 24 1990)*, in (1991) 42:1 Intern'l Digest of Health Legis. 60-64 (hereinafter Germany: *Embryo Protection Law*); Switzerland: Genetics and Assisted Procreation *Amendment to the Federal Constitution, August 13 1992*, (1992) 43:4 Intern'l Digest of Health Legis. 745-746 (hereinafter Switzerland: *Amendment to Federal Constitution*); Norway: *Act Relating to the Application of Biotechnology in Medicine, supra,* note 54; In France, see *Loi no 94-653 du 29 juillet 1994 relative au respect du corps humain*, Journal Officiel de la République Française 30 juillet 1994, 11056-11059, section 1 (hereinafter France: *Loi no 94-653*) in (1994) 45:4 Intern'l Digest of Health Legis. 498 and also *Loi no 94-654 du 29 juillet 1994 relative au don et à l'utilisation des éléments et produits du corps humain, à l'assistance médicale, à la procréation et au diagnostic prénatal*, Journal Officiel de la République Française 30 juillet 1994, 11060-11068 in (1994) 45:4 Intern'l Digest of Health Legis. 473.

be made against the State for accessibility to genetic testing or for genetic information under another rubric of human rights law, that of the right to the highest attainable standard of health.

(c) Right to the Highest Attainable Standard of Health

The concept of a right to health is relatively modern. While traditionally understood as being "the absence of illness", the preamble of the 1946 constitution of the World Health Organization, to which Canada subscribes, also speaks of the highest attainable standard of health and defines health as "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity".[58]

Furthermore, it is interesting to note that international texts have not used a uniform approach in treating the right to health. Hence, while the *Universal Declaration* mentions "the right to a standard of living adequate for the health and well-being" of an individual and his family,[59] the *International Covenant on Economic, Social and Cultural Rights* proclaims "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health".[60]

Following the approach used by the *International Covenant on Economic, Social and Cultural Rights*, the recently adopted international *Convention on the Rights of the Child* [61] adopts positive and broad wording in its Article 24(1), which states:

> States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.

This article includes, within the concept of the child's right to the highest attainable state of health, the obligation of State Parties "to ensure appropriate pre-natal and post-natal care for mothers".[62] It also reiterates the rights and protection afforded to mothers before and

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58 World Health Organization Constitution (1948) 14 U.N.T.S. 185.

59 *Universal Declaration*, *supra*, note 13 at Article 25(1).

60 *Supra*, note 14, Article 12.1; Knoppers, *supra*, note 2. For an excellent study of the right to health, see: H. Fuenzalida-Puelma, S. Scolle Conner, eds, *The Right to Health in the Americas, A Comparative Constitutional Chapter* (Sci. Pub. No. 509) (Washington: Pan American Health Organization, 1989), and more particularly on the right to health see: T. Buergenthal, "International Human Rights Law and Institutions" at 3-16; and with respect to the notion of the right to health as a progressive right see: H. Fuenzalida-Puelma, S. Scolle Conner, "Summary and Analysis" at 541-678, particularly the discussion on pp. 602ff and 664ff.

61 GA Res. 44/25, UN GAOR, Sess., UN Doc. (1989). Canada signed the Convention on May 28, 1990 and ratified it on December 11, 1991.

62 *Ibid.*, art. 24(d).

during pregnancy.[63] This wording could have particular ramifications for the early detection and treatment of childhood genetic diseases. It is possible that, within the purview of this right, the State Parties to this Convention could take whatever measures are necessary to ensure as much as possible preconception and prenatal conditions favouring the birth of a healthy child.

Other international and regional treaties or charters place the right to health in the larger context of economic, environmental, and social rights or the right to access to services without discrimination.[64] Irrespective of whether this right is interpreted as imposing a positive obligation on the State or simply as a social ideal, there is no doubt that the attainment of the best possible state of health is necessarily dependent on the structuring of this larger societal context so as to ensure universality of services, accessibility and quality of care. Obviously, there can be no right to be born healthy since disease and death are a natural part of the human condition. A more appropriate term might be the right to health protection.[65] In short, the legal ambit of both "the right to reproductive health care" and children's "rights to health inheritance"[66] remains to be established.

An example of state involvement for the protection of the health of individuals are the newborn screening programs that have as their rationale the prevention of genetic disorders.[67] The protection of the health and life of newborns is achieved through these programs by early

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63 *Ibid.* Note that the Preamble reiterates the wording of the *Declaration of the Rights of the Child* to the effect that "the child, by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection, before as well as after birth."

64 For example, the *Univèrsal Declaration*, *supra*, note 13, at article 25(1) refers to the "right to a standard of living adequate for the health and well-being...including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control". Article 24 of this Declaration further provides that "everyone has the right to rest and leisure, including reasonable limitations of working hours and periodic holidays with pay". See *International Covenant on Economic, Social and Cultural Rights*, *supra*, note 14, Articles 2(2), 3, 10(2) and 10(3); See also the text of the *American Declaration on the Rights and Duties of Man*, as reproduced in Inter-American Commission on (March 29 1979) O.A.S./ser.L/V/II.23/doc.21rev.6., Article XI (hereinafter *American Declaration*). See also T. Buergenthal, *supra*, note 60; H. Fuenzalida-Puelma, S. Scolle Conner, *supra*, note 60 at 664ff.; M. Bélanger, *Droit international de la santé* (Paris: Economica, 1989) at 19-42.

65 Fuenzalida-Puelma & Scolle Conner, *supra*, note 60, 596. In a Quebec case, *Engstrom* c. *Courteau*, [1986] R.J.Q. 3048-3063 (C.S.), after an overview of wrongful birth and wrongful life cases in the U.S., the Court noted, at 3062: "L'examen de ces causes les plus pertinentes et autres citées ou consultées révèle que les tribunaux américains, en règle générale, n'ont pas maintenu les poursuites de l'enfant handicapé, ne reconnaissant pas un droit fondamental à l'enfant de naître en tant qu'un homme sain et normal". See also *Cherry* v. *Borsman,* 75 DLR (4th) 668, 94 DLR (4th) 487, in which the facts clearly describe a wrongful birth case although this was not raised.

66 Cook, *supra*, note 51, at 667.

67 Knoppers & Laberge, eds, *Genetic Screening: From Newborns to DNA Typing* (Amsterdam: Excerpta Medica, 1990); S.J. Fox, D. Young, "International Protection of Children's Right to Health: The Medical Screening of Newborns" (1991) 11 Boston College Third World Law Journal 1. M. Hirtle, *Le dépistage génétique des nouveau-nés: aspects juridiques et applications* (Montreal: Éditions Yvon Blais Inc., 1995).

detection ensuring treatment for what are debilitating and life-threatening disorders.[68] Currently, newborn screening programmes are carried out in most industrialized countries and an international consensus exists as to their beneficence for this population.[69]

Recent scientific advances in human genetics permit the detection of carrier status of late onset, non-treatable disorders and provoke conflicting views as to the ambit of basic liberties and corresponding duties at the individual, familial, and collective levels.[70] The potential impact of these advances will require review of allocation of health resources and, more importantly, it will require a redefinition of the concept of health itself. Such issues arise since the expression of the right to the highest attainable standard of health is also dependent on the recognition of other fundamental human rights such as the right to life, liberty, and security.

(d) Right to Life, Liberty, and Security

The fundamental human rights most closely linked to health, medical treatment, and thus, ultimately, to human genetics, are those of the rights to life, to liberty, and to security of the human person.[71] According to the *Universal Declaration*, any limitation or interference with the exercise of these basic human rights can only be "determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a

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68 See National Academy of Sciences, *Genetic Screening: Programs, Principles and Research* (Washington: National Research Council, 1975); J.P. Farriaux & J.L. Dhondt, eds, *New Horizons in Neonatal Screening* (Amsterdam: Exerpta Medica, 1994).

69 See D.C. Wertz & J.C. Fletcher, "Proposed: An International Code of Ethics for Medical Genetics" (1993) 44 Clinical Genetics 37-43; B.M. Knoppers, "Ethical, Social and Legal Aspects of Genetics in Medicine" in WHO Technical Report Series, Scientific Group on the Control of Hereditary Disease, (Geneva: WHO, forthcoming); L.B. Andrews, *State Law and Regulations Governing Newborn Screening* (Chicago: American Bar Association, 1985); Illinois Department of Public Health, *An Overview of Newborn Screening Programs in the United States and Canada* (Illinois, 1993).

70 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research, *Screening and Counselling for Genetic Conditions* (Washington: U.S. Government Printing Office, 1983); U.S. Congress Office of Technology Assessment, *Mapping Our Genes* (Washington: U.S. Government Printing Office, 1988); Committee on Assessing Genetic Risk, Institute of Medicine, *Assessing genetic Risks: Implications for Health and Social Policy* (Washington D.C.: National Academy Press, 1994); Nuffield Council on Bioethics, *Genetic Screening Ethical Issues* (London: Nuffield Council on Bioethics, 1993); Science Council of Canada, *Genetics in Canadian Health Care*, Report No. 42 (Ottawa: Ministry of Supply and Services, 1991); M. Gobert, "Incidences juridiques des progrès biologiques et médicaux sur le droit des personnes" in Commission nationale consultative des droits de l'homme, *1989: Les droits de l'homme en question* (Paris: La Documentation française, 1989) 317-337, 330; A. Capron, "Decoding the Human Genome: Dominion, Deontology and Deconstruction" in International Conference on Bioethics, *The Human Genome Sequencing: Ethical Issues* (Brescia, Italy: CLAS, 1989), 154; and S. Rodota, "Diagnosis, Secrecy, Destiny" in International Conference on Bioethics, *The Human Genome Sequencing: Ethical Issues* (Brescia, Italy: CLAS, 1989), 180.

71 *Universal Declaration*, *supra*, note 13, Article 3; *International Covenant on Civil and Political Rights*, *supra*, note 14, articles 6.1 and 9.1; *European Convention*, *supra*, note 3, Articles 2 and 5. For a study of interpretation by the courts of the various international instruments according these rights, see Sieghart, *supra*, note 10.

democratic society".[72] In contrast with the freedom from torture or from slavery, which are absolute rights,[73] the right to life can be limited by the need to protect public order, the general welfare, or other fundamental rights. Hence, "it may therefore be said that international human rights law assigns a higher value to the quality of living as a process, than to the existence of life as a state".[74] This is particularly evident in the decisions on abortion.[75] Most countries have accepted the presence of severe genetic disorders as an indicator for legal abortion (even in the third trimester), but this particular genetic criterion has not been the object of international or domestic human rights law.[76] It does, however, indicate an international recognition of the human suffering that accompanies genetic disease, of the respect for personal liberty and privacy, and the hierarchy of values that comes into play. The increased capacity to diagnose genetic disorders *in utero* at earlier stages (and at the pre implantation stage) will no doubt limit the number of situations in which late abortions (often on viable foetuses[77]) are requested. Nevertheless, the moral and societal choices remain the same.

In the Canadian context, the rights to life, liberty, and security are entrenched under section 7 of the *Canadian Charter,* which also provides for the protection of these rights from interference by public authorities.[78] As in international law, these rights are not absolute and

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72 *Universal Declaration*, *supra*, note 13, Article 29(2).

73 See, for example, *European Convention*, *supra*, note 3, Articles 3 and 4; *International Covenant on Civil and Political Rights*, *supra*, note 14, Articles 7 and 8; *Universal Declaration*, *supra*, note 13, Articles 4 and 5.

74 Sieghart, *supra*, note 10, at 130.

75 R. Cook, "U.S. Population Policy, Sex Discrimination and Principles of Equality under International Law" (1987) 20:1 N.Y. Univ. J. of Int'l Law and Pol. 93-142; B.M. Knoppers, "Reproductive Technology and International Mechanisms of Protection of the Human Person" (1987) 32 McGill L.J. 337-358, 352; B. Stark, "International Human Rights and Family Planning: A Modest Proposal" (1989) 18:1 Denver Journal of Law and Policy 59-81; *Morgentaler*, *supra*, note 28; *Tremblay v. Daigle*, [1989] 2 S.C.R. 530.

76 See B.M. Knoppers & I. Brault, *La loi et l'avortement dans les pays francophones* (Montréal: Les Éditions Thémis, 1989); S. Le Bris, Essai de théorie générale sur le diagnostic génétique avant la naissance (Thèse de doctorat, Université de Rennes, 1995); Knoppers & LeBris 1993a, *supra*, note 53.

77 B.M. Knoppers, "Comparative Abortion Law: The Living Abortus" in J.K. Mason, ed., *Paediatric Forensic Medicine and Pathology* (London: Chapman and Hall, 1989) at 381-397.

78 For an overview of section 7 see P. Garant, "Fundamental Justice and Fundamental Rights" in G.A. Beaudoin & E. Ratushny, *The Canadian Charter of Rights and Freedoms, 2d Edition* (Toronto: Carswell, 1989) 330-385; J. Laskin et al, eds, *The Canadian Charter of Rights Annotated* (Ontario: Canada Law Book, 1982-); J. Gosselin & G. Laporte, *La Charte canadienne des droits et libertés: Les grands énoncés de la Cour suprême* (Cowansville: Les Éditions Yvon Blais Inc., 1993) vol. 2. See also *Fleming* v. *Reid* (*Litigation Guardian)* (1991) 82 D.L.R. (4th) 298, (1991), 4 O.R. (3d) 74 (C.A.); rev'g (1990), 73 O.R. (2d) 169 (Dist. Ct), where certain provisions of Ontario's mental health legislation violated the security of the person interest enshrined in s. 7. In striking down the legislation, the court, at 312, stated the following:

> The common law right to bodily integrity and personal autonomy is so entrenched in the traditions of our law as to be ranked as fundamental and deserving of the highest order of protection. The right forms an essential part of an individual's security of the person and must be included in the liberty interests protected by s. 7. Indeed, in my view, the common law right to determine what shall be done with one's body and the constitutional right of security of the person, both of which are founded on the belief in the dignity and autonomy of each individual, can be treated as coextensive.

can be limited in a free and democratic society,[79] or where consistent with the principles of fundamental justice under section 7 itself.[80]

Liberty is often understood as being synonymous with autonomy. In the medical context, it protects both freedom of research as well as the freedom of persons to freely participate in and benefit from scientific advances. It can also encompass the freedom to make personal decisions surrounding procreative choice though most texts subsume reproductive decision-making under the right to privacy.[81] In the North American context, the right to liberty has been defined to include a wider variety of interests including freedom of personal choice in matters of marriage and family life.[82] In Canada, however, the scope of the right to liberty has been described, by Madam Justice Wilson, as including "the right to make fundamental personal decisions without interference from the state".[83]

In the context of genetic medicine this right might find application since, "[d]ecisions about one's genetic health or that of one's offspring would certainly fall within the ambit of personal decisions".[84] For example, "[m]andatory screening of adults or adolescents to determine whether they are carriers of genetic disease would clearly be an interference with this right. The dignity and self-respect of those persons would be affected. Such legislation

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79 Under section 1 of the *Charter* and according to the principles developed in *R.* v. Oakes, *supra*, note 28.

80 Contrasting views persist on the process to be applied for violations under section 7. Justice Lamer in the *Prostitution Reference*, [1990] 1 S.C.R. 1123 at 1140 considers that there must be two components before finding a violation of rights protected under section 7: first, there must be a breach of one of the rights protected under section 7 and, secondly, there must be a violation of principles of fundamental justice. However, in the *Morgentaler* case, *supra*, note 28, at 174, Madam Justice Wilson considered that, once a violation of a right under section 7 was demonstrated, then one must consider the extent to which the legislature can "deprive" individuals of the right to liberty according to principles of fundamental justice and "the extent to which it can put 'limits' on it under section 1". See also the more recent Supreme Court case of *Rodriguez* v. *B.C. (A.G.)*, *supra*, note 28, where the majority concluded that, in determining whether fundamental justice was infringed, courts must look to the interests of both the person claming the infringement and the interest of society as a whole. In her dissent, Madam Justice McLachlin argued that societal interests should be taken into account only in the s. 1 stage of the Charter analysis, that is, once it has been determined that a Charter right has been violated. See also *R.* v. *Swain*, (1991) 1 S.C.R. 933 where Chief Justice Lamer for the majority also concluded that the "balancing of societal interests against the individual right guaranteed by s. 7 should only take place within the confines of s. 1 of the Charter". Note that to date Canadian Courts have found security of the person violations where the state either directly compels medical intervention against the wishes of an individual (*Fleming*, *supra*, note 78) or prohibits access to medically required treatment (*Morgentaler, supra*, note 28).

81 See *infra*, this ch., sec 2(e).

82 Sieghart, *supra*, note 10, 143.

83 *Morgentaler*, *supra*, note 28, 166 (*per* Madam Justice Wilson dissenting). In coming to this conclusion, Madam Justice Wilson cited with approval the United States Supreme Court decisions recognizing procreative autonomy as a fundamental constitutional right (see, for example, *Skinner* v. *Oklahoma*, 316 U.S. 535 (1942); *Griswold* v. *Connecticut*, 381 U.S. 479 (1965); and *Roe* v. *Wade*, 410 U.S. 113 (1973)) and applied the foureenth amendment privacy and equal protection doctrine to the realm of marriage and reproduction (the relevant portion of which reads: "no State shall...deprive any person of life, liberty or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws").

84 Knoppers, *supra*, note 2, 35.

would infringe section 7 because that legislation "require[s] a person...to go through an identification process on pain of...[a sanction] for failure to comply".[85] However, as with fingerprinting, any infringement by legislation of the rights found under section 7 could still be seen as being in accordance with the principles of fundamental justice and therefore not in violation of that section.

More importantly, the right to the liberty and security of the person requires, as with any other type of interference on one's body, that the consent of the person be obtained prior to any participation in either human genetic diagnosis, research, or therapy.[86] This respect for the inviolability of the human person has been specifically dealt with in the context of medical experimentation and medical ethics.[87] The new human genetics, however, affects all citizens and includes research, screening, testing, therapy, and prevention. It has a specificity not foreseen by most texts, which might place it outside of the protective ambit of international texts on ethics and human experimentation. Indeed, the right to security of the person takes on a new interpretation if it were to be equated with the right not only to consent to or refuse medical research or treatment but also to control what is done with one's DNA and with the information it contains (extending even beyond one's lifetime).[88] This interpretation, which takes the right to security beyond the notion of physical intrusion, was upheld by the Supreme Court of Canada.[89] The international character of the human genome project and the need for international collaboration and sharing of information and DNA through informatics and DNA banking will perhaps force this specific issue to the forefront

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85 *Ibid.*

86 See generally on the requirement of obtaining informed consent prior to medical treatment: Ellen I. Picard, *Legal Liability of Doctors and Hospitals in Canada, 2nd ed.* (Toronto: Carswell Legal Publications, 1984) 41-141; *Malette v. Shulman* (1990), 72 O.R. (2d) 417 (C.A.), aff'd (1987), 63 O.R. (2d) 243 (H.C.); *Fleming v. Reid* , *supra*, note 78.

87 See generally, Medical Research Council of Canada, *Guidelines on Research Involving Human Subjects 1987*, (Minister of Supply and Services Canada: Ottawa, 1987); The *Declaration of Helsinki*, adopted at the 18th World Medical Assembly, 1964, and amended by the 29th Assembly in Tokyo (1975), the 35th Assembly in Venice (1983), and the 41st Assembly in Hong Kong (1989) and reproduced in (1990) 41:3 Intern'l Digest of Health Legis. 530-533; Z. Bankowski, R.J. Levine, eds, *Ethics and Research on Human Subjects - International Guidelines* (Geneva: Council of International Organizations of Medical Sciences, 1993) (hereinafter CIOMS, *Ethics and Research on Human Subjects*); Council of Europe, *Recommendation No. (90)3*, *supra*, note 23; See *infra*, this ch., sec. 3.

88 See L.B. Andrews, "Public Choices and Private Choices: Legal Regulation of Genetic Testing" in T.F. Murphy & M.A. Lappé, eds, *Justice and the Human Genome* (Berkeley: University of California Press, 1994) 46-74; See also L.B. Andrews, "DNA Testing, Banking and Individual Rights" in Knoppers & Laberge, eds, *supra*, note 67, 217-242.

89 *Mills v. R.*, [1986] 1 S.C.R. 863, *per* Lamer J. at 919-920, cited in *Morgentaler*, *supra*, note 28, by Chief Justice Dickson at 55: "security of the person is not restricted to physical integrity; rather, it encompasses protection against 'overlong subjection to the vexations and vicissitudes of a pending criminal accusation'... These include stigmatisation of the accused, loss of privacy, stress and anxiety resulting from a multitude of factors, including possible disruption of family, social life and work." See also Justice Wilson at 173. Reaffirmed in *Rodriguez* v. *B.C. (A.G.)*, *supra*, note 28, at 588 (Sopinka J.): "There is no question, then, that personal autonomy, at least with respect to the right to make choices over one's physical and psychological integrity, and basic human dignity are encompassed within security of the person, at least to the extent of freedom from criminal prohibitions which interfere with these."

and require the elaboration of more explicit forms of domestic and international legal protection.[90] For the present, in the absence of both domestic and international legal texts specific to the protection of personal freedoms in the context of the new genetics, recourse in the case of State violation can also be sought under the rubric of the right to privacy and family life.

(e) Right to Privacy and Family Life

The concept of the right to respect for one's private and family life found under international[91] and domestic law is an expanding one, "the word 'liberty' being nowadays more narrowly confined to physical freedom from arrest, imprisonment, or other restrictions on free movement".[92] In Europe, case law has "developed the right of privacy into an important adjunct for the protection of the other [European] Convention rights, in support of the principle of respect for the dignity, autonomy, independence and integrity of the individual which underlies them all".[93] Accordingly, the right to privacy also comprises "the right to establish and develop relationships with other human beings".[94] Nevertheless, the claim to respect for private life is reduced to the extent that the individual brings his private life into contact with public life or other protected interests recognized under law.[95] Signatory states to the *Universal Declaration* or to the *International Covenant on Civil and Political Rights* are "on notice that they must be able to present compelling reasons for asserting their interests over individuals' claims to privacy in their personal and family lives, and states must offer more than ideological grounds for restraining individuals' exercise of private and family integrity".[96] The protection of the family by the State is also guaranteed under various

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90 See Council of Europe, *Draft Bioethics Convention*, *supra*, note 3; The International Human Genome Organization (HUGO) is committed to the principle of free exchange of materials and information. see C.R. Cantor, "HUGO Physical Mapping" (1990) 345 Nature 106; UNESCO, *Preliminary Outline of a Declaration*, *supra*, note 5.

91 Universal Declaration, supra, note 13, Article 12; American Declaration, supra, note 64, Art. V; International Covenant on Civil and Political Rights, supra, note 14, art 17(1); American Convention, supra, note 14, Article 11; European Convention, supra, note 3, Article 8.

92 Sieghart, *supra*, note 10, at 146.

93 *Ibid.*, at 147.

94 Sieghart, *supra*, note 6, at 313.

95 See Sieghart, *supra*, note 6, at 313; B.M. Knoppers, "Reproductive Technology and International Mechanisms of Protection of the Human Person" (1987) 32 McGill Law Journal 337-358, 355.

96 Cook, *supra*, note 51, at 665. *The International Covenant on Civil and Political Rights*, *supra*, note 14, Article 17 provides that "[n]o one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence" and that everyone enjoys "the right to the protection of the law against such interference". *Universal Declaration*, *supra*, note 13, Article 12.

international instruments.[97] Respect for one's family life has been interpreted mainly as meaning the right to assistance and protection.[98]

In Canada, "courts have deliberately held open the question of whether there exists in Canadian law a right to privacy comparable to that recognized in the United States, where restrictive legislation on abortion and contraception has been held unconstitutional for violating the right to privacy".[99] Yet, the Supreme Court of Canada has interpreted section 8 of the Charter as protecting the privacy interest and particularly so as it pertains to medical information.[100] In a more recent case,[101] in which a blood sample was obtained legally but then used in relation to another sexual assault of which the accused was neither informed nor accused, the Supreme Court reiterated that "[o]bviously a person does not cease to have a reasonable expectation of privacy in his or her blood at any time while that blood is still inside his or her body". The Court continued by recalling two precedents[102] that recognize that consent to the taking of blood can be limited for certain purposes only and that "[t]his concept reveals a link between the scope of a valid consent and the scope of the accused's knowledge in relation to the consequences to that consent".[103]

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97 American Declaration, supra, note 64, Article V; American Convention, supra, note 14, Article 11(2); Convention on the Rights of the Child, supra, note 61, Article 9; International Covenant on Economic, Social and Cultural Rights, *supra*, note 14, Article 10.

98 See Sieghart, *supra*, note 6, at 204; *Universal Declaration*, *supra*, note 13, article 16.3; The recent *Convention on the Rights of the Child*, *supra*, note 61, reiterates the need to respect the child within its family and also the family itself as a social limit, Article 9. It also accords the right of privacy to the child, Article 16. *The International Covenant on Civil and Political Rights*, *supra*, note 14, Article 23(4); See also Knoppers, *supra*, note 95, 354-355. See *infra*, this ch., sec. 2(f).

99 Cook, *supra*, note 51, at 664.

100 See *R.* v. *Dyment*, *supra*, note 36, 417, where LaForest J. states that s. 8 goes beyond protection against unreasonable searches and seizures to guarantee the right to be secure against unreasonable search and seizure. Further, privacy is not limited to property. Three zones of privacy are identified, and protected: (1) territorial (property); (2) person (protecting the dignity against the moral invasion of the person caused by a search); and (3) informational privacy, assuming that all information belongs to the person himself, for him to communicate or retain, by choice. Also, it is emphasised that privacy must be maintained in order to preserve patient confidence in the Canadian medical system, and its administration. Exchange of information between physicians and the police should not be permitted, as there is the expectation that any sample taken by a physician is to be used only for medical purposes, and that it would be kept private. To use the sample for any reason other than those for which it was gathered violates the personal autonomy of the individual. See also *Hunter v. Southam*, [1984] 2 S.C.R. 145; *R.* v. *Dersch*, [1993] 3 S.C.R. 768; *R.* v. *Colarruso*, [1994] 1 S.C.R. 21.

101 *R.* v. *Borden*, Supreme Court of Canada, [1994] S.C.J. no 82.

102 *R.* v. *Dyment*, *supra*, note 36, and *R.* v. *Colarusso*, *supra*, note 100.

103 See *R.* v. *Borden*, *supra*, note 101, per Iacobucci J. It is important to take note of the reasons of Chief Justice Lamer who specifies on this issue that "[t]he s. 8 jurisprudence from this Court has recognised that a consent to provide a blood sample for *medical purposes* is a limited consent and that s. 8 is implicated if the sample so taken is to be converted to police use. I do not take this to mean that other limitations on subsequent use arise from the form or circumstances of consent. The inquiry under s. 8 involves a balancing of the reasonable expectation of privacy and other societal interests, including effective law enforcement. This balancing is highly sensitive to the context and circumstances in which the search or seizure is conducted." Lamer J. considers the taking of the blood sample in this case was an unlawful seizure since the right to be

In the context of human genetics however, this right to privacy and family life will centre chiefly around access to genetic services and information by individuals and their family members or, *a contrario*, refusal of access to information to protect the privacy and family life of those same individuals.[104] Do spouses or future spouses or indeed anyone intending to have a child with another person have the right to knowledge of the genetic status or "health" of that person? The debate surrounding donor anonymity in medically assisted conception may serve as a precursor to the discussion of the right to know medical information about a genetically-related person.[105] Indeed, in spite of its reticence to press for regulation of the private sector, the 1990-91 annual report of the Canadian Privacy Commissioner went further than this problem of possible legal duties in the intra-familial sharing of sensitive information and stated that "the privacy implications of genetic testing demand that the government consider whether there should be direct regulation of any private sector uses of this highly intrusive technology".[106]

Apart from the familial context, privacy concerns may arise from paternity testing and DNA profiling for forensic purposes.[107] More widespread concern about the right to privacy may arise from the protection of automated information, a situation that has been addressed in Europe.

In 1981, the Council of Europe passed the *Convention for the Protection of Individuals with regard to the Automatic Processing of Personal Data.*[108] The object of this Convention was to strengthen data protection, that is, "the legal protection of individuals with regard to automatic processing of personal information relating to them".[109] Of particular interest is the recognition in the explanatory report that "'information power' brings with it a corresponding social responsibility of the data users in the private and public sector".[110] This Convention also recognizes the particular nature of medical data and includes it within the special

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informed of the reason of detention and right to counsel had been violated and thus a valid consent to the seizure could not be obtained.

104 See *infra,* ch. 8.

105 Nevertheless, a few reports on medically assisted conception did create a positive obligation to warn the child of the genetic health of the donor for diseases appearing after the donation or a right for the child to ask for genetic information. See Knoppers & LeBris (1993a), *supra*, note 53; and *infra,* ch. 8.

106 Privacy Commissioner of Canada, *Annual Report* (Ottawa: Supply and Services Canada, 1991) at 20.

107 We will consider the former issue *infra,* ch. 5. Forensic testing, not being of provincial jurisdiction, will not be treated in this study. See however, Swiss Institute of Comparative Law, *Human genetic analysis and the protection of personality and privacy, International colloquium* (Zurich: Schulthess, Polygraphischer Verlag, 1994).

108 European Treaty Series, No 108, and reproduced in Council of Europe, *Explanatory Report on the Convention for the Protection of Individuals with regard to the Automatic Processing of Personal Data* (Strasbourg: Council of Europe, 1981) (hereinafter Council of Europe, *Explanatory Report*).

109 Council of Europe, *Explanatory Report*, *ibid.* at 5.

110 *Ibid.* The Explanatory Report does not constitute on instrument providing an authoritative interpretation of the Convention, although it might be of such nature as to facilitate the understanding of the provisions of the Convention.

categories of data excluded from automatic processing "unless domestic law provides appropriate safeguards".[111] These safeguards, however, vary from country to country and, in addition, do not address the peculiarities of genetic data as distinct from other medical data.[112] The Council of Europe's 1992 *Recommendation on Genetic Testing and Screening for Health Care Purposes* reiterates that "[t]he collection and storage of substances and of samples, and the processing of information derived therefrom, must be in conformity with...the Convention".[113] Finally, according to article 9 of the *Convention for the Protection of Individuals with regard to the Automatic Processing of Personal Data*, the need for the sharing of personal data in scientific research does not raise any particular issues when there is obviously no risk of an infringement of the privacy of the data subjects.[114]

Given the expansion of genetic diagnostic technology and informatics, the issue of research in human genetics and the transboundary sharing of genetic information or DNA goes well beyond the limited protection that such general provisions can offer. Indeed, merely a year following the 1981 *Convention for the Protection of Individuals with regard to the Automatic Processing of Personal Data*, the Council of Europe foresaw the need for "principles governing the preparation, storage, safeguarding and use of genetic information on individuals, with particular reference to protecting the rights to privacy of the persons concerned".[115]

Within Canada, no province has distinguished general medical data from genetic data nor made special provision for the latter in either the public or private health care sectors. While it could be argued that genetic information is only "highly sensitive" medical information,[116] it has certain characteristics that mandate additional legal safeguards and protection. This is because genetic data are by definition familial in nature and thus necessarily pertain to persons other than the proband or patient. Furthermore, they must be stored over time and be accessible in some way to other family members, even after the death of the person concerned.[117] Current federal and provincial legislation relevant to privacy

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111 *Ibid.*, Article 6.

112 See *infra,* ch. 9.

113 Principle 8, which follows with: "In particular, in genetic screening and testing or associated genetic counselling personal data may be collected, processed and stored only for the purposes of health care, diagnosis and disease prevention, and for research closely related to these matters." Council of Europe, Committee of Ministers, 470th Meeting, *Recommendation No. (92)3 on Genetic Testing and Screening for Health Care Purposes* (hereinafter *Recommendation No. (92)3 on Genetic Testing*). See also Council of Europe, Committee of Ministers, 442nd Meeting, *Recommendation No. (90)13 on Prenatal Genetic Screening, Prenatal Genetic Diagnosis and Associated Genetic Counselling*, (hereinafter *Recommendation No. (90)13 on Prenatal Genetic Screening*) Principle 11. See also *infra,* ch. 9.

114 However, the *Recommendation No. (92)3 on Genetic Testing*, *ibid.*, requires at Principle 12 that research projects involving medical genetic data be carried out under the direct supervision of a responsible physician.

115 *Recommendation 934 (1982)*, *supra*, note 17, Article 7(d).

116 See *infra,* ch. 9.

117 Only the Quebec *Act Respecting Health Services and Social Services*, Q.S., 1991 c. 42, provides at section 23 that "persons related by blood to a deceased user may be given communication of information contained

rights and the confidentiality of medical information is limited.[118] The right of persons to be informed of the existence of an automated medical data file in a government institution covered by such legislation and to have access to the information contained therein will also raise particular problems in the genetic context. Any taking of a genetic family history will necessarily be medical and "familial". It would be very difficult and legally questionable to inform all third parties of the fact that information related to them was provided by another family member.[119] Indeed, it could be argued that the communication of such a fact might constitute an infringement of the "right not to know"[120] or *a contrario*, create a duty to know.[121] Thus, the question of whether a particular obligation rests on family members, or indeed, on the physician, to communicate information to identified "at risk" family members remains open.

The international human genome mapping effort makes the issue of the right to privacy an international one,[122] and it should also be addressed at that level. For, in the context of human genetics, where the establishment of genetic pedigrees often requires international collaborative research, the concern is not only with the protection of personal and familial privacy, but also with the ensuing "genetically-informed" reproductive choices and the freedoms associated therewith.

(f) Right to Marry and Found a Family

The exponential increase of genetic knowledge will undoubtedly affect the right to marry and found a family. Interestingly, the provision for the right to marry and to found a family in the *Universal Declaration*, "originated in reaction to the Nazi racial and reproductive policies"[123] and provides that "men and women of full age, without any

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in his record to the extent that such communication is necessary to verify the existence of a genetic or hereditary disease".

118 See *infra*, ch. 9.

119 See *Recommendation No. (92)3 on Genetic Testing*, *supra*, note 113, Principle 9 provides "[h]owever, in the case of a severe genetic risk for other family members, consideration should be given, in accordance with national legislation and professional rules of conduct, to informing family members about matters relevant to their health or that of their future children". See also, Nuffield Council on Bioethics, *supra*, note 70 at 42-43; Committee on Assessing Genetic Risk, Institute of Medicine, *supra*, note 70, at 267.

120 The Council of Europe, *Draft Bioethics Convention*, *supra*, note 3, recognises such a right at Article 12, which provides that "[e]veryone has the right to respect for private life in the field of health. Individuals are entitled to know any information collected about their health. However, the wishes of individuals not to be so informed shall be observed."

121 M. Shaw, "Conditional Prospective Rights of the Fetus" (1984) 5 J. Legal Med. 63-116. See also, *infra*, ch. 9.

122 The adoption of the "International Guidelines for Ethical Review of Epidemiological Studies" in Z. Bankowski, J.H. Bryant, J.M. Last, eds, *Ethics and Epidemiology: International Guidelines* (Geneva: Council for International Organizations of Medical Sciences, 1991), makes this point albeit obliquely. See Council of Europe, *Draft Bioethics Convention*, *supra*, note 3, Article 12. UNESCO, *Preliminary Outline of a Declaration*, *supra*, note 5.

123 Cook, *supra*, note 51, 663.

limitation due to race, nationality or religion, have a right to marry and to found a family" and that "[m]arriage shall be entered into only with free and full consent".[124] Furthermore, States Party to the *International Covenant on Economic, Social and Cultural Rights* are required to recognize that: "[t]he widest possible protection and assistance should be accorded to the family".[125] The *European Convention* also provides for the right to found a family without any express restrictions but the case law surrounding abortion has held that this right is not absolute and a State may impose limits if they are consistent with human rights provisions.[126] It is unclear whether such a right goes beyond its traditional negative aspects, that is, non-governmental interference, to include provision for access to genetic testing.

The legal right to family planning is not enumerated specifically in most legally enforceable national, regional, and international instruments. However, this right can be derived from those basic human rights that are included in legally binding conventions. For example, the human right to family planning is included as an element of non-discriminatory rights in the *Convention on the Elimination of all Forms of Discrimination Against Women*, as men and women have "the same right to decide freely and responsibly on the number and spacing of their children and to have access to the information, education and means to enable them to exercise these rights".[127] It has been suggested that family planning is a necessary precondition for the basic human right of equal protection of the laws and a necessary consequence of the inherent right to human dignity.[128]

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124 *Supra*, note 13, Article 16(1). This right is also found in various other instruments: *International Covenant on Civil and Political Rights*, *supra*, note 14, Article 23; *American Declaration*, *supra*, note 64, Article VI; *American Convention*, *supra*, note 14, Article 17.

125 *Supra*, note 14, Article 10(1).

126 See Article 12, *European Convention*, *supra*, note 3; See Knoppers, *supra*, note 95, 355; See also Stark, *supra*, note 75.

127 December 18, 1979, G.A. Res. 34/180, U.N. Doc. A/34/146, [1982] C.T.S. 31, Article 16.

128 R.J. Cook, *Human Right in Relation to Women's Health* (Geneva: World Health Organization, 1993) at 47; R.J. Cook, "International Protection of Women's Reproductive Rights" (1992) 24:647 New York University J. of Int'l Law and Politics 688-696. On the importance of reproductive choice being considered as a right see: Stark, *supra*, note 75, at 75ff. One theory of procreative liberty has been thus described by an American expert, J.A. Robertson, "Procreative Liberty and Human Genetics" (1990) 39 Emory Law Journal 695, and "The Potential Impact of the Human Genome Project on Procreative Liberty", in G.J. Annas & Sherman Elias, eds, *Gene Mapping - Using Law and Ethics as Guides* (New York: Oxford University Press, 1992) 215: The theory of procreative liberty would support recognition of the right of couples to screen their embryos prior to implantation, and to discard (or eventually treat) embryos which are genetically defective. Also, since couples have the primary interest in genetic offspring, they should have final authority over whether their embryos produce offspring. This freedom to make decisions to beget, bear and rear offspring is a central component of most theories of personal autonomy. In procreative freedom, the government has a duty to refrain from barring persons from obtaining and making use of genetic information in reproduction, recognised in the constitutional protection accorded procreative choice. Further, the government has a duty to protect consumers of genetic information by assuring that genetic information is accurately provided by competent professionals, by licensure and certification. Also, the government would provide access to genetic services to those who lack insurance coverage. With procreative liberty would come procreative responsibility. However, if "irresponsible" reproductive behaviour is followed, it can be argued that no harm is caused to the offspring. If there is no reasonable possibility of a healthy birth, then conceiving and

The identification of "at risk" individuals and all the more so of at risk couples will make the protection of the right to marry and found a family particularly problematic. Voluntary carrier testing is available in most industrialized countries.[129] In some countries or populations at an identifiable risk for certain genetic diseases, the church has played a substantial role in prenuptial screening. To take a well known example, the Cypriot population while not subject to state control over proposed marriages between carriers for thalassemia, imposes a more indirect form of surveillance through the pre-marital genetic screening done by the Church.[130] Similarly, because of its religious prohibition of abortion, the Orthodox Jewish community has instituted a registry for Tay-Sachs carriers.[131] While no country has yet undertaken systematic population carrier screening for the more common genetic disorders such as cystic fibrosis, research projects on testing for carrier status in young adults are under way.[132]

Generally, states have not imposed genetic screening as a legal condition of marriage. Recently, one American state, however, began requiring county clerks to distribute to all persons applying for a marriage license, a brochure concerning inherited metabolic diseases.[133] Reports of the French National Ethics Committee, prepared in 1985 and 1991, also suggested the implementation of systemic prenuptial carrier testing.[134]

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proceeding to term does not harm the unavoidably handicapped offspring. Concern for the offspring thus could not justify coercive public policies designed to prevent or minimize such births. Individuals, not government, should decide how to use genetic knowledge in reproduction. However, see at the other end of the spectrum of procreative liberty the recent Chinese legislation as reported in (1995) 46:1 Intern. Digest of Health Legis. 39-42, which amends an earlier version referring to terms such as "eugenics" and "inferior births" and provides that medical and health care establishments are responsible for assuring the protection of the pregnant woman's health and that where the fetus is found to be abnormal, that is, suffering from a serious genetic disease or deficiency, the physician is to explain the situation to the couple concerned and sugggest that the pregnancy be terminated for medical reasons. See V. Rich, "China's Law on Maternal and Infant Health", (1995) Lancet 1497 who points out that these concessions may be merely cosmetic since the respect accorded doctors in the Chinese tradition and the family planning policy which grants considerable maternal incentives to those who comply with it, make it unlikely that many women will refuse a "recommended" abortion.

129 Knoppers & Laberge, eds, *supra*, note 67.

130 A. Cao et al., "Prevention of Homozygous ß-Thalassemia by Carrier Screening and Prenatal Diagnosis in Sardinia" (1981) 33 Am. J. Hum. Genet. 592-605, 602; A. Cao, "Antenatal Diagnosis of ß-Thalassemia in Sardania" in Z. Bankowski & A.M. Capron, eds, *Genetics, Ethics and Human Values: Human Genome Mapping, Genetic Screening and Gene Therapy*, (Council for International Organizations of Medical Sciences: Geneva, 1991) 72-79.

131 G. Cowley, "Made to Order Babies" (1990) 114:27 Newsweek Special Issue 94-100; See for example E. Broide et al., "Screening Carriers of Tay-Sachs Disease in the Ultraorthodox Ashkenazi Jewish Community in Israel" (1993) 47 American Journal of Medical Genetics 213-215.

132 F. Kaplan et al., "Cystic Fibrosis Carrier Screening by DNA Analysis: A Pilot Study of Attitudes Among Participants" (1991) 49 Am. J. Hum. Genet. 240-242.

133 An Act (Public Act 86-884, Laws 1989) in relation to sexually transmitted diseases amending named Act, Sept. 1989); Ill. Rev. Stat. Ann. 40 para. 204 (West. Supp. 1986) (premarital exam for sickle cell trait); Alaska Code § 25.05.101 (1983) (premarital exam for the presence of infectious or heritable disease).

134 Avis sur les problèmes posés par le diagnostic prénatal et périnatal, Rapport du 13 mai 1985, in Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé, *Xe Anniversaire: Les avis de 1983*

Furthermore, it is doubtful that the "right to found a family" is the equivalent of a legal right to procreate under any conditions and by any means with no regard for the consequences for future generations. What of the right of the child to the enjoyment of the best state of health possible?[135] Does the legal duty not to harm through one's fault create a duty to prevent the transmission of serious defects by improving one's genetic condition through therapy or avoiding such transmission through selection, recourse to donated gametes or embryos or even elimination? Any obligation to future generations may remain a moral obligation. Indeed, it could be argued that the preservation of freedom and privacy in reproductive decision-making is essential to avoid State interference and ultimately State control, thus paradoxically mandating State protection of such freedom. Nevertheless, until such genetic knowledge relevant to personal reproductive choice becomes widespread, the most immediate concern might well be the acquisition of such knowledge by third parties and the need to prevent "genetic" discrimination and provide for the assurance of equality under section 15 of the *Charter*.

(g) Right to be Free from Discrimination and to Equal Treatment

Central to international instruments,[136] "[n]ondiscrimination and equality are at the very heart of the assertion of dignity and opportunity, of recognition and respect".[137] According to one author, "[t]he international law instruments differ from section 15 of the *Charter* in that the *Canadian Charter* provides substantive equal protection, whereas the international instruments only secure individuals from discrimination with respect to rights and freedoms set out therein or in related treaties or declarations".[138] Section 15 of the *Canadian Charter* enumerates distinctions such as race, national or ethnic origin, colour, religion, sex, age or mental or physical disability, and, these categories not being closed, enable the Courts to apply this protection to unspecified forms of discrimination. Proof of intention to discriminate is not required. Indeed, according to the Supreme Court of Canada, "discrimination may be described as a distinction, whether intentional or not but based on grounds relating to personal characteristics of the individual or group, which has the effect of imposing burdens, obligations or disadvantages on such individuals or groups not imposed

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à 1993, 79-93, 81; Avis sur l'application des tests génétique aux études individuelles, études familiales et études de population (Problèmes des "banques" de l'ADN, des "banques" de cellules et de l'informatisation des données) 24 juin 1991, in Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé, *Xe Anniversaire: Les avis de 1983 à 1993*, 297-305, at 298.

135 Convention on the Rights of the Child, supra, note 61, Art. 24.

136 Universal Declaration, supra, note 13, Articles 2, 7; International Covenant on Civil and Political Rights, supra, note 14, Articles 2(1), 3, 26; International Covenant on Economic, Social and Cultural Rights, supra, note 14, Articles 2, 3; European Convention, supra, note 3, Article 14; American Convention, supra, note 14, Article 1, 24; American Declaration, supra, note 64, Article II; International Convention on the Elimination of All Forms of Racial Discrimination, (1969) 660 U.N.T.S. 195, [1970] C.T.S. 2; Convention on the Elimination of All Forms of Discrimination Against Women, supra, note 127.

137 M. Cohen, "Towards a Paradigm of Theory and Practice: The Canadian Charter of Rights and Freedoms - International Law Influences and Interactions" (1986) C.H.R.Y. 47 at 67.

138 W. Schabas, International Human Rights Law and the Canadian Charter (Toronto: Carswell, 1991) at 116.

upon others, or which withholds or limits access to opportunities, benefits, and advantages available to other members of society".[139]

A second source of protection against discrimination in Ontario is the *Human Rights Code.*[140] Although similar approaches may be applied to section 15 of the *Canadian Charter* and the *Human Rights Code*, several differences between these two instruments exist. The *Human Rights Code* protects against discrimination by government but also by private persons, including corporations, in matters within the provincial jurisdiction. Secondly, certain rights are broader under the *Human Rights Code,* as it does not contain limits that can be "demonstrably justified in a free and democratic society" as found under the *Canadian Charter.*[141] The *Human Rights Code* provides for protection from discrimination in terms of services, accommodation, contracts and employment on grounds of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sex, sexual orientation, age, marital status, family status or handicap. Discrimination because of handicap is further defined as the reason "the person has or has had, or is believed to have or to have had"[142] a condition due to bodily injury, birth defects or illness, a condition of mental retardation, a learning disability, a mental disorder or, finally, a disability for which compensation is claimed. And, "even in the case of perceived disability, the disability in question must fit within the definition of handicap".[143]

Studies in the United States have shown that there exist instances of discrimination as a consequence of genetic testing on individuals, primarily in the context of employment and insurance.[144] Despite important structural differences between the United States and Canada,

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139 *Andrews* v. *Law Society of British Columbia*, *supra*, note 28 at 174, *per* McIntyre. See also: *R. v. Turpin*, [1989] 1 S.C.R. 1296; *McKinney* v. *University of Guelph*, [1990] 3 S.C.R. 229; *R.* v. *Swain*, *supra*, note 80; *Symes* v. *Canada*, [1993] 4 S.C.R. 695; *Rodriguez* v. *B.C. (A.G.)*, *supra*, note 28.

140 R.S.O. 1990, c. H.19.

141 Section 1; See generally A. Bowland, C. Nakatsu, J. O'Reilly, *The Annoted Human Rights Code 1993* (Scarborough, Ontario: Carswell, 1993) at 1-2.

142 *Ibid.*, Section 10(1).

143 Bowland, Nakatsu, O'Reilly, *supra*, note 141 at 55. In the case *Jerome* v. *Demarco* (1992) No. 438 (Ont. Bd. of Inquiry), persons with AIDS are "handicapped" within the literal words and the spirit of the *Human Rights Code*. It is also interesting to note that in an unreported Quebec case, the court accepted asymptomatic HIV infection a "handicap" under Quebec *Charter of Human Rights and Freedoms*. As reported in D. Patterson, "Québec Court Finds Asymptomatic HIV Infection a Charter "Handicap" (1994) 1:1 Canadian HIV-AIDS Policy & Law Newsletter, 4, the court considered the definitions of "handicap" in the human rights acts of Ontario and Nova Scotia which include the subjective perception of disability or handicap, and, inspired by these broad definitions, found "that the defendant's perception of the plaintiff as being able to easily transmit a mortal illness constituted a handicap..." in Quebec. A similar conclusion had been reached in the British Colombian Human Rights Tribunal in *Biggs* v. *Hudson* (1988) 9 C.H.R.R. D/5391.

144 P.R. Billings *et al.*, "Discrimination as a Consequence of Genetic Testing" (1992) 50 Am J. Hum. Gen. 476-482; N.A. Holtzmann & M.A. Rothstein, "Invited Editorial: Eugenics and Genetic Discrimination" (1992) 50 Am. J. Hum. Genet. 457-459; M.R. Natowicz, J.K. Alper, J.S. Alper, "Genetic Discrimination and the Law" (1992) 50 Am. J. Hum. Genet. 365-475. For an overview of theses issues see Knoppers, *supra*, note 2 at 48-51. See, also, *infra,* chs. 5 and 6.

the American experience may serve as a preview of potential discrimination based on genetic characteristics,[145] especially at an era of accelerated expansion of knowledge and novel applications in the field of genetics. In the Canadian context, we must consider the applicability of the *Canadian Charter* and the Ontario *Human Rights Code* to cases of discrimination due to genetic characteristics on the basis of either disability or an unspecified ground, or handicap.

By analogy, the genetic makeup of a person may be considered as inherent and personal to that person as, for example, his or her race, ethnic origin, ancestry, colour, or sex. Genetic characteristics are not chosen. Social perceptions of genetic illness, of carrier status and the general incomprehension of the probabilistic and prognostic character of genetic conditions and information make this an area ripe for discrimination. Furthermore, while those actually ill with genetic disorders could be covered under "disability", those who are "at risk" or who belong to the "healthy ill"[146] (unless pertaining to certain identifiable ethnic group or race) are not necessarily protected.[147] In short, even though not expressly enumerated under section 15 of the *Canadian Charter*, individuals or groups with genetic disorders, predispositions, or susceptibilities, could be protected given the "indicia of discrimination such as stereotyping, historical disadvantage or vulnerability to political and social prejudice".[148] The Supreme Court of Canada has emphasized the need to look not only at the criteria of impugned legislation, but at the larger social, political, and legal context to see whether differential or even equal treatment will result in inequality.[149] Finally, the right to equality before the law and to equal protection of the law without any discrimination does not render all differences in treatment discriminatory if such differentiation or differential impact is based upon reasonable and objective criteria found under section 1 of the *Canadian Charter*. Rights and

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145 In the United States reference has been made to the term "genetic discrimination" *per se* distinguishing it from discrimination based on disability. See Natowicz, Alper, Alper, *ibid.* at 466: "Genetic discrimination can be defined as discrimination against an individual or against members of that individual's family solely because of real or perceived differences from the "normal" genome in the genetic constitution of that individual.... We distinguish genetic discrimination from discrimination based on disabilities caused by altered genes by excluding from the former category, discrimination against an individual who at the time of the discriminatory act is affected by the genetic disease." See also Billings *et al.*, *supra*, note 144, at 477.

146 L. Gostin, "Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers" (1991) 17:1&2 Am. J. Law & Med. 109 at 118-119; Billings *et al.*, *supra*, note 144, at 478.

147 Yet, even classifying genetic conditions and risks as "disabilities" has tremendous social implications. See Knoppers, *supra*, note 2, at 40: "However, the inclusion of genetic handicap in the general notion of handicap is problematic. It might mean that being genetically different is equivalent to having a disability because the distinction between a 'difference' and a 'handicap' is not always clear. Another view is preferable, namely, that we are all genetically equal because we all have certain genetic differences from one another."

148 *R. v. Turpin*, *supra*, note 139 at 1333.

149 *Ibid.*, at 1331.

freedoms may also be limited "in circumstances where their exercise would be inimical to the realization of collective goals of fundamental importance".[150]

Similarly, the protection provided by the *Ontario Human Rights Code* against discrimination on the grounds of handicap or perceptions of handicap[151] could apply to persons who are affected by, "at risk", or carriers of genetic disorders. In its 1991 report on *Genetics in Canadian Health Care*, the Science Council of Canada considered that the "existing Charter of Rights and Freedoms and provincial human rights legislation are likely to be sufficient to protect individuals from discrimination on the basis of genetic knowledge".[152]

Indeed, government policies affecting genetic health or opportunity or prohibiting certain forms of manipulation or therapy could well be justified considering the universal and communal nature of the gene pool and the intergenerational aspects of intervention. Such an approach could be mandated though the international recognition of the human genome as the common heritage of mankind so as to ensure its global protection and management in the common interest of humanity, while not unduly infringing on individual rights. As already mentioned, the UNESCO International Bioethics Committee is working towards the international recognition of the human genome as the common heritage of the human species (or as more recently revised, humanity). It also provides for the protection of the individual from unjustified discrimination based on his or her genetic characteristics.[153]

In addition to the various national and international provisions protecting human rights, medical ethics, a secondary, although more contemporary, source of normative obligations must be discussed.

3. MEDICAL ETHICS

In 1948, the General Assembly of the World Medical Association adopted the Declaration of Geneva wherein admission as a member of the medical profession required the promise to "maintain the utmost respect for human life from its beginning even under threat and...to not use...medical knowledge contrary to the laws of humanity".[154] One year prior, the trials of war criminals led to the concept under international law of crimes against humanity,[155] and, in the judgment of the Doctors' Trial, to the articulation of ten principles on

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150 *Oakes*, *supra*, note 28 at 136; See also reasons of Lamer C.J. (dissenting) in *Rodriguez* v. *B.C. (A.G.)*, *supra*, note 28, at 547-549.

151 See Bowland, Nakatsu, O'Reilly, *supra*, note 141 at 55.

152 (Ottawa: Minister of Supply and Services, 1991) at 72.

153 UNESCO, Preliminary Outline of a Declaration, supra, note 5, section 5.

154 World Medical Association, *Declaration of Geneva (1948)*, adopted 2nd General Assembly (Geneva, Switzerland), amended by 22nd World Medical Assembly 1968 (Sydney, Australia), and the 35th World Medical Assembly 1983 (Venice, Italy), reprinted in D. Giesen, *International Medical Malpractice Law* (Tubingen, Germany: Mohr Publ, 1988) at 728 (Appendix II).

155 C. Ambroselli, *L'Éthique médicale, Que sais-je* (Paris: Presses Universitaires de France, 1988); See also Schabas, *supra*, note 138 at 110-111 for a discussion on the inclusion of crimes against humanity under the *Canadian Charter*.

human experimentation now known as the Nuremberg Code.[156] The justification for protecting common humanity, or protecting "man as man" is that "every individual should be treated as an end in himself, not as an instrument for others".[157] The importance of such protection was further emphasized by the International Covenant on Civil and Political Rights, which states that "[n]o one shall be subjected to torture or to cruel, inhumane or degrading treatment or punishment. In particular, no one shall be subjected without his free and informed consent to medical or scientific experimentation."[158]

In 1964, the World Medical Association adopted the *Declaration of Helsinki,*[159] which set forth recommendations guiding physicians in biomedical research involving human subjects. The 1989 revised version of the *Declaration of Helsinki* states that physicians must respect "the right of the research subject to safeguard of his or her integrity".[160] This Declaration, while recognizing the validity and necessity for experimentation involving human subjects, distinguished between therapeutic and non-therapeutic research, set the framework of principles for biomedical research involving human subjects, and concluded that "[i]n research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject".[161] These general principles on research with humans were further refined in the 1982 CIOMS *Proposed International Guidelines for Biomedical Research Involving Human Subjects* revised in general in 1993.[162] Guidelines for the more specific area of epidemiological studies was addressed separately in 1991,[163] but it must be noted that the latter guidelines do not cover human genetics.

In 1988, however, delegates to an international summit of the seven industrialized nations were convened to discuss the specific topic of bioethics and human genome sequencing.[164] They "agreed that there are no intrinsic limitations to the acquisition of the

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156 See M.A. Grodin, "Historical Origins of the Nuremburg Code" in G.J. Annas & M.A. Grodin eds, *The Nazi Doctors and the Nuremburg Code: Human Rights in Human Experimentation* (New York: Oxford University Press, 1992) 121-144, and at A. 2 of the Nuremburg Code. Also reprinted in Giesen, *supra*, note 154 at 727.

157 McDougal et al., *supra*, note 6 at 461.

158 *Supra*, note 14, Article 7.

159 The original version of the Declaration of Helsinki was adopted by the 18th World Medical Assembly, 1964 (Helsinki) and amended by the 19th World Medical Assembly, 1975 (Tokyo), the 35th World Medical Assembly, 1983 (Venice), and finally 41st World Medical Assembly, 1989 (Hong Kong). The revised version is reprinted in (1990) 41(3) Intern'l Digest of Health Legis. 530-533. Also reprinted in Annas & Grodin eds., supra, note 156 at 339-342.

160 *Ibid.*, Principle I (6).

161 *Ibid.*, Principle III (4).

162 Council for International Organizations of Medical Sciences, International Ethical Guidelines for Biomedical Research Involving Human Subjects, 1993, in CIOMS, *Ethics and Research on Human Subjects, supra*, note 87 at 231ff.

163 Council for International Organizations of Medical Sciences, "International Guidelines for Ethical Review of Epidemiological Studies", 1991, in Z. Bankowski, J.H. Bryant & J.M. Last eds, *Ethics and Epidemiology: International Guidelines* (Geneva: CIOMS, 1991) at 167ff.

164 International Conference on Bioethics, The Human Genome Sequencing: Ethical Issues (Brescia, Italy: CLAS International, 1989).

human genome and that research in this area should be strongly encouraged".[165] More specific to the issue of alteration of human genetic heritage and the human rights of the person, the delegates agreed "that there are neither medical indications nor ethical justifications for intentional genetic manipulation of human germline cells at this time".[166] Later that year, in a workshop on international co-operation for the human genome project, the participating scientists acknowledged in the "Valencia Declaration", their responsibility to help ensure that genetic information be used only to enhance the dignity of the individual, a declaration that was reaffirmed in 1990.[167] This appeal to ensure the preservation of human dignity within the context of advances in human genetics has been taken up in a more formal way, by the International Movement for Scientific Responsibility, an international non-governmental organization of concerned scientists.[168]

One of the goals of the International Movement is to encourage the United Nations to add a new article to the Universal Declaration of Human Rights. This article would state that scientific knowledge should be used only to serve the dignity, integrity, and future of mankind. Furthermore, no one should impede its acquisition. If there is agreement on this principle, they intend to ask governments to request that the United Nations discuss the adoption of three ancillary positions: (1) all sources of energy must be used for the benefit of mankind without harm to the biosphere; (2) considering the current state of the science, the genetic patrimony of mankind should not be modified in a hereditary fashion ; and (3) the human body in all it elements, cells, tissues and organs has no price and cannot be the source of profit.[169] This laudable initiative has the merit of seeking international legal recognition of the universal and yet unique character of the "genecity"[170] of humanity. The limits on alteration of the genetic patrimony, however, are linked to the current state of the science, a flexible criterion, but also an ambiguous one.

In a 1990 CIOMS meeting on human genome mapping in Tokyo, a broad consensus on a number of central issues was reached by the participants, who agreed to the *Declaration of Inuyama.*[171] This Declaration stated that "efforts to map the human genome present no inherent ethical problems" but that such efforts must adhere to "ethical standards of research

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165 *Ibid.*, at 291.

166 *Ibid.*

167 II Workshop on International Cooperation for the Human Genome Project, *Valencia Declaration*, *supra*, note 4. See also the International Workshop on Legal Aspects of the Human Genome Project, 1993, *Bilbao Declaration*, reprinted in (1994) 45:2 Intern'l Digest Health Legis. 234-237.

168 The Mouvement Universel de Responsabilité Scientifique. See Dausset, *supra*, note 4, at 6.

169 *Ibid.*, at 6: "Les connaissances scientifiques ne doivent être utilisées que pour servir la dignité, l'intégrité et le devenir de l'Homme. Nul ne peut en entraver l'acquisition".

170 This term was used by A. Capron "Unsplicing the Gordian Knot: Legal and Ethical issues in the 'New Genetics'" in A. Milunsky & G. Annas, eds, *Genetics and the Law III* (New York: Plenum, 1985) at 23-24.

171 Reprinted in Z. Bankowski & A.M. Capron, eds, *Genetics, Ethics and Human Values: Human Genome Mapping, Genetic Screening and Gene Therapy*, (Geneva: Council for International Organizations of Medical Science, 1991) at 1.

and that knowledge gained will be used appropriately".[172] Furthermore, the need for ethical sensitivity in policy making was raised. With respect to genetic testing, the Declaration recalls the need to respect principles of autonomy and confidentiality, but specifies that the "central objective...should always be to safeguard the welfare of the person tested".[173] The Declaration clearly distinguishes between gene therapy on somatic cells and on germ cells. Alterations of somatic cells should be evaluated like other innovative therapies, by independent ethical review committees, especially if gene therapy involves children, and intervention should be limited to conditions that cause significant disability.[174] While not proscribing modification of germ cells *per se*, continued discussion is considered essential and the safety of germ-line therapy must be well established before it is undertaken. The Declaration affirms that researchers and therapists have a strong responsibility to ensure that the techniques they develop are used ethically.[175]

In 1992, the World Medical Association adopted a declaration specifically dealing with the Human Genome Project.[176] Recommending ethical review while the Human Genome project is still in its early stages, the WMA stated that guidelines are needed to prevent discrimination and the genetic stigmatization of those at risk. The guidelines of the WMA promote universal access to genetic services, international communication and transfer of technology and knowledge, autonomy of the person, disclosure to third parties only with consent, and, finally, the protection of confidentiality.

In 1995, the Council of the Human Genome Organization (HUGO) asked its HUGO-ELSI Committee to provide guidelines and procedures that would address the concerns raised by the Human Genome Project and ensure that ethical standards are met as the Project proceeds. Based on four guiding principles—recognition that the human genome is part of the common heritage of humanity; adherence to the international norms of human rights; respect for the values, traditions, culture, and integrity of participants; and acceptance and upholding of human dignity and freedom—the HUGO-ELSI Committee provided recommendations governing competence, communication, consent, choices, confidentiality, collaboration, conflict of interest, compensation, and continual review.[177]

4. CONCLUSION

The recent recommendations on medical ethics and advances in biotechnology of the Council of Europe, and of certain international governmental and non-governmental

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172 *Ibid.*, recommendation I.

173 *Ibid.*, recommendation IV.

174 *Ibid.*, recommendation V.

175 *Ibid.*, recommendation VII.

176 *Declaration on the Human Genome Project*, 44th World Medical Assembly, 1992 (Marbella, Spain) World Medical Association, reprinted in (1993) 44(1) Intern'l Digest of Health Legis. 150-152.

177 B.M. Knoppers, M. Hirtle, S. Lormeau, "Ethical Issues in International Collaborative Research on the Human Genome: The Human Genome Project (HGP) and the Human Genome Diversity Project (HGDP)" June 1996, Genomics (in press).

organizations, reveal the gradual emergence of both a regional and an international consensus. Our review of the ethical, social, and legal parameters to be applied to scientific advances generally and more recently to those in the area of human genetics, serves to illustrate a commonly held patrimony of spiritual and moral values that gradually may find their translation into legal norms. Irrespective of the scientific advance under scrutiny, these international and regional texts and recommendations promote the recognition and protection of the commonly held values of respect for human dignity, privacy, autonomy, and family life. These international commitments establish legal obligations for Canada as a nation and serve as an interpretative source for the *Charter*.[178] The *Charter* itself could be considered an implementing device for these international obligations.[179] There is also a presumption that Canada does not intend to violate international obligations and that, whenever possible, the *Charter* should be interpreted in a manner consistent with these obligations.[180] Yet, while it is the duty of governments to enact legislation to implement treaties covering matters within their jurisdiction when such legislation is necessary, these values, as currently enunciated in human rights law, lack the specificity to force national governments that have ratified these instruments to act to protect the human genome.[181]

The national dimension of the concerns raised by genetic testing may justify federal interference in areas of general public concern as well as in those areas in which certain activities are considered morally reprehensible to all Canadians. [182] While "health" falls within provincial powers, "where the dimension of the problem is national rather than local in nature" or "arises in the context of a public wrong", the response may be federal.[183] Although it may seem to be an option between broad anti-discrimination legislation or narrow sector by sector "genetic-specific" legislation, federal or provincial affirmation of the applicability of human rights legislation generally, and of the protection of those with carrier status specifically, may be all that is required.

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178 According to A. M. Kindred, *International Law Chiefly as Applied and Interpreted in Canada*, 4th ed. (Toronto: E. Montgomery, 1987), some of its international obligations may even form part of our domestic law (Human rights at 635ff.); See *Re Public Service Employee Relations Act*, [1987] 1 S.C.R. 313 at 345: "I believe that the Charter should generally be presumed to provide protection at least as great as that afforded by similar provisions in international human rights documents which Canada has ratified".

179 M. Cohen and A. Bayefsky, "The Canadian Charter of Rights, Freedoms and Public International Law" (1983) Can. Bar Rev. 265. See also Cook, *supra*, note 51, at 670-671 regarding enforceability.

180 E. Mendes, "Interpreting the *Canadian Charter of Rights and Freedoms*: Applying International and European Jurisprudence on the Law and Practice of Fundamental Rights" (1982) 20 Alta L. Rev. 383.

181 See generally Council of Europe, *Europe and Bioethics: Proceedings of the 1st Symposium of the Council of Europe on Bioethics* (Strasbourg: Council of Europe, 1989).

182 See *Schneider v. R.*, [1982] 2 S.C.R. 112, at 114: Parliament is not precluded from "legislating in relation to public health, viewed as directed to the protection of the national welfare" under the peace, order and good government power. Its jurisdiction over criminal law may provide another avenue.

183 *Ibid.*, at 141. This federal response may be long in coming despite the urgent need to clarify both human rights and medical ethics in the context of genetic testing particularly given that health treatment and choices of individuals are currently affected and that the cumulative impact of these choices is collective.

CHAPTER 4

PROPERTY RIGHTS AND GENETICS

1. INTRODUCTION

Recent biotechnological advances involving use of human cells and tissues have raised unforeseen questions about personal dominion and control over one's body parts once they are separated from the body. Whereas the humanitarian value of organ donations made in order to aid scientific research or sick individuals has long been recognized in Canada, other biological matter has been perceived as abandoned with little economic value. Underground markets for donor organs, the creation of DNA and cell banks as well as the development of profitable cell lines used by the pharmaceutical industry have since proven otherwise.

Commercial exploitation of the human body and its genetic components is thus becoming a pressing issue since the ability to read such components "genetically" has altered the symbolic and social significance of human tissues. Moreover, the legal characterization of human genetic material remains unclear and, as such, the control and rights that interested parties may exert over it are equally uncertain. Both researchers/physicians and participants/patients are left to negotiate the terms of such rights, and this within relationships in which the balance of power lies with the medical community. Currently then, all parties as well as the biotechnology industry are left without direction.

In law, property[1] is characterized by a bundle of rights or incidents attached to objects, whether they are tangible or intangible,[2] that determine the manner and degree to which they can be controlled. The most common incidents of property are the rights to possess, to exclude, to alienate, to use, to enjoy, to manage, and to destroy.[3] Far from being absolute,

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1 The concept of property is not easily defined. At common law, "property" refers to the collection of legal rights recognized in an object, not the object itself. R.W. Marusyk and M.S. Swain, "A Question of Property Rights in the Human Body" (1989) 21 Ottawa L. Rev. 351, at 355.

2 Tangible property denotes an actual physical object and includes real property such as property in land or things attached to the land and some real property, such as property in chattel. Intangible property is an interest arising from legal relationships between people and includes such things as business goodwill, life insurance policies and intellectual property. Thus property describes the legal relations of individuals with regard to use and enjoyment of tangible and intangible objects. *Black's Law Dictionary*, 6th ed. (Minnesota: West Publishing Co., 1990).

3 M.M. Litman and G.B. Robertson, "Reproductive Technologies: Is a Property Regime Appropriate?" in *Overview of Legal Issues in New Reproductive Technologies* (Volume 3 of the Research Studies, Royal Commission on New Reproductive Technologies) (Ottawa: Minister of Supply and Services Canada, 1993) 233, at 244.

these rights are often limited or even excluded by statute or by the Common Law, in different combinations, according to varying social policy considerations and moral concerns.[4]

In instances in which numerous incidents of property are restricted, particularly the rights of exclusion and alienation, the object in question may lose its property label or may be considered quasi-property.[5] It has been suggested that human reproductive material should fall into this category.[6] Whether or not human genetic material should be similarly characterized remains to be determined. The quasi-property characterization has been applied in a number of cases regarding material derived from the human body. For instance, in the American *Hecht* case, human sperm was considered property for the purposes of a disposition in the testator's will.[7] Similarly, in Canada, a widow was held to have a limited "quasi-property" interest in her husband's corpse for the purpose of burial.[8]

Apart from the American case of *Moore* v. *Regents of the University of California,*[9] there is little jurisprudence that deals with the application of property doctrines to human genetic material. The issue of abandonment of human material (*res derelictae*) has been addressed in the case of *Venner* v. *State,* in which it was noted that an individual may have property rights in his or her waste material, thus perhaps inferring that it is not easily abandoned.[10] While case law in this particular area is sparse at this point in time, there is little doubt that questions of the legal characterization of human genetic material[11] will be finding themselves before the courts at an increased frequency. The time is therefore ripe for clarifications.

In order to situate possible Canadian approaches to property rights in genetic material, a brief overview of how other jurisdictions are currently addressing this issue is necessary. In 1991, the World Health Organization prepared a set of Guiding Principles on Human Organ Transplantation based on the position that the human body and its parts cannot be the subject of commercial transactions. Accordingly, giving and receiving payment for organs should be prohibited as well as any other commercial dealing in this field. In that same year, the World

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4 *Ibid.*, at 243.

5 A quasi property right is a limited property right. The owner of the property has some but not all of the sticks in the bundle of property rights. In the case of corpses, for example, courts have recognized a quasi property right that entitles the family to possession of the corpse and enables the family to dispose of it, but prevents the family from selling the corpse. See *infra,* note 59, and accompanying text.

6 *Supra,* note 3, at 246-247.

7 *Hecht* v. *Superior Court of California (Kane)*, 20 Cal. Rptr. (2d) 275 (Ct. App. June 17, 1993).

8 See *Edmonds* v. *Armstrong Funeral Home*, [1931] 1 D.L.R. 676 (Alta. S.C.) and *Philipps* v. *Montreal General Hospital*, (1908) 33 S.C. 483.

9 *Moore* v. *Regents of the University of California,* 249 Cal. Rptr. 494 (Cal. App. 2 Dist. 1988) ; 271 Cal. Rptr. 146 at 150, 793 P. 2d 479 (1990)(S.C. Cal.), *cert. denied*, 111 S. Ct. 1388 (1991) (Hereinafter *Moore*).

10 *Venner v. State,* 354 A2d 483 (Maryland, 1976).

11 Such as that found in DNA, cells and tissues.

Health Assembly adopted a resolution endorsing these guiding principles.[12] Several other international bodies, in relation to genetic research and the bodily material and information derived therefrom, have endorsed a personal rights approach and have thus asserted the importance of respecting the will of persons participating and their right to decide on the extent of participation.[13]

At the regional European level, the Council of Europe in its recommendation on genetic testing and screening for health care purposes, adopted a similar position, requiring a person's permission for further use of any sample collected for a medical or scientific purpose.[14] Further, the 1995 draft of the Bioethics Convention affirmed the principle of non-commercialism of the human body and its parts (save for tissue considered as waste, such as hair and nails), and stated that they could not be a source of profit for the individual from whom the human material originated or for any third parties such as hospitals.[15]

Several European nations have specifically addressed the issue of ownership of bodily material once removed from the body. As early as 1991, the French National Ethical Consultative Committee for the Life and Health Sciences issued an opinion on the non-commercialization of the human genome. It affirmed this principle by asserting that "all information contained in the human genome belongs to the common heritage of mankind; it is a field of knowledge that cannot be subjected to monopoly".[16] The Committee thus adopted a position that would ensure access for the entire scientific community to all DNA sequences deposited in data banks.[17] This principle of non-commercialization of the human body, its

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12 Forty-fourth World Health Assembly, Resolution WHA44.25 as cited in (1991) 42(3)International Digest of Health Legislation 389-413. In 1989, the Forty-second World Health Assembly adopted resolution WHA42.5 specifically preventing the purchase and sale of human organs and calling upon Member States to take appropriate measures to prevent such trafficking. Also see Council of Europe, C.M., 287th Meeting, *Resolution (78)29 on the Harmonisation of Legislations of Member States Relating to the Removal, Grafting and Transplantation of Human Substances,* which covers the removal of tissue from living and dead donors for therapeutic, diagnostic and scientific purposes.

13 World Medical Association, "Declaration on the Human Genome Project (1992) " (1993) 44:1 Intern'l Digest of Health Legis. 150; World Health Organization, *Hereditary Diseases*, WHO Technical Report Series (Geneva:1995) (forthcoming); UNESCO, *Revised Outline of a Declaration on the Protection of the Human Genome*, International Bioethics Committee (Paris: 7 March 1995).

14 Council of Europe, C.M., 470th meeting, *Adopted*, Rec. R92(3) on Genetic Testing and Screening for Health Care Purposes, princ 13 (a): "Samples collected for a specific medical or scientific purpose may not, without permission of the persons concerned or the persons legally entitled to give permission on their behalf, be used in ways which could be harmful to the persons concerned."

15 Council of Europe, *Draft Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Bioethics Convention and Explanatory Memorandum* (Strasbourg: July 1994) art. 11 as amended in February 1995 (Council of Europe, P.A., first part of its session (30 January -3 February) on the Draft Bioethics Convention, *Adopted*, Opinion No. 184 on the Draft Bioethics Convention).

16 French National Ethical Consultative Committee for the Life and Health Sciences, "Opinion on the Non-Commercialisation of the Human Genome", as cited in (1993) 44:1 International Digest of Health Legislation at 131.

17 *Ibid.*

organs, tissues, cells, and products, was laid down in legislation in 1994.[18] Similarly, a recent report from the Health Council of the Netherlands[19] emphasized the right to self-determination over one's body and its parts and endorsed the principle of non-commercialism, while expressing the belief that regulation on the storage and use of human tissue is needed,[20] a position adopted by the Danish Council of Ethics.[21]

Although the Nuffield Council on Bioethics also recommended that the removal of donated human tissue should operate on a non-commercial basis, it is unclear whether a person from whom tissue is removed retains any claim over such tissue.[22] It was recommended that the law should proceed on any claim over tissue by examining the basis of the consent given by the person to the procedure that resulted in the removal of the tissue, and not on the basis of a property claim. It further indicated that consent to medical treatment should be regarded as abandonment of the removed tissue.

In the United States, both the American Society of Human Genetics and a Proposed Genetic Privacy Act indicate that identifiable DNA remains the property of the "donor" or "sample source" respectively.[23] Conversely, a recent preliminary draft report presented to the

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18 *Loi no 94-654 du 29 juillet 1994 relative au don et à l'utilisation des éléments et produits du corps humain, à l'assistance médicale à la procréation et au diagnostic prénatal*, (30 juillet 1994) Journal Officiel de la République française 11060-11068, amending article L.665-13 du *Code de la santé publique*: "Aucun paiement, quelle qu'en soit la forme, ne peut être alloué à celui qui se prête au prélèvement d'éléments de son corps ou à la collecte de ses produits.", (Translation as cited in (1994) 45(4) International Digest of Health Legislation at 474): "No payment, in any form whatsoever, may be granted to a person who submits to the removal of elements from his body or the collection of products thereof." See also *Loi no 94-653 relative au respect du corps humain* (29 July 1994) Journal Officiel de la République Française, Lois et Décrets, No. 175, 11056-11059, Article 16-1: " Le corps humain, ses éléments et ses produits ne peuvent faire l'objet d'un droit patrimonial". (Translation as cited in (1994) 45(4) International Digest of Health Legislation at 498): "The human body, its elements, and its products may not be the subject of a right of inheritance" (sic). Note the report of the French Ministry of Higher Education and Research on *The Intellectual Protection of the Results of Research on the Human Genome, Cell Collection and DNA Sequencing Data* (Paris: June 10, 1994) , made prior to the adoption of these laws, which made recommendations based on the principle of "non-proprietorship of the elements and products of the human body." (at 11).

19 Health Council of the Netherlands, Committee on Human Tissue for Special Purposes, *Proper Use of Human Tissue* (The Hague: Health Council of the Netherlands, 1994) at 52-53, and for a more general debate see 31-40.

20 *Ibid.*, at 93-96.

21 The Danish Council of Ethics, *Ethics and Mapping of the Human Genome* (Copenhagen: The Danish Council of Ethics, 1993) at 29.

22 Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues* (London: Nuffield Council on Bioethics, April 1995), par. 13.24 and rec. 8. Note that, in accordance with most European policy positions, commercialization of tissue procurement is prohibited except for certain removed body products such as hair and nails that may be bought and sold since they are waste products.

23 American Society of Human Genetics, "DNA Banking and DNA Analysis: Points to Consider" (1987) *American Journal of Human Genetics* 781 (ASHG, point 2) recommended that "DNA banked for private and familial purposes should be considered "the property of the depositor unless otherwise stipulated" and proposed that guidelines to that effect should be enacted in order to create a uniform standard of deposit,

NIH-ELSI working group on informed consent for genetic research on stored tissue samples specified that sources "retain no property interest in their samples or expectation of profit from any commercial products that might be developed".[24]

In the Canadian context, the 1991 Science Council of Canada report on genetics in Canadian Health Care endorsed a gift-based donorship philosophy and warned against its being undermined by the recognition of property rights in genetic material.[25] A 1993 research study presented to the Canadian Royal Commission on New Reproductive Technologies indicated as follows: [26]

> [P]olicy is the core determinant of which objects are property and which are not... Implicit in this form of analysis is the recognition that property is instrumental or purposive in character. Property is recognised to exist and is juristically engineered with a view to promoting policies and interests.

While some may find it morally abhorrent and dehumanizing to treat bodies, tissues, and cells as things or commodities, others argue that a property framework may be the most efficient way of protecting the rights of patients, of research subjects and of the deceased.[27] A discussion of the controversial and highly publicized *Moore* case follows below. We then turn to examine the potential of and the difficulties raised by recognizing pure property rights[28] in the human body through an analysis of relevant policy considerations, as well as existing Ontario and Canadian legislation and case law relative to both dead and living bodies and tissues. Finally, we consider the viability of a number of alternative approaches to these issues.

2. THE *MOORE* CASE

In 1976, John Moore was diagnosed with a rare form of cancer known as hairy-cell leukemia. His physician at UCLA recommended a splenectomy as the best course of

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access and withdrawal, among facilities offering such services." Note that the word "donor" is a misnomer since it implies a gift which is inappropriate for this property position; see also G.J. Annas, L.H. Glantz and P.A. Roche, Proposal: The Genetic Privacy Act and Commentary (Boston: 28 February 1995) sec. 3(n).

24 E. Wright Clayton, "Informed Consent for Genetic Research on Stored Tissue Samples" (March 1995) (rec. 3) (forthcoming).

25 Science Council of Canada, *Genetics in Canadian Health Care*, Report 42, (Ottawa: Minister of Supply and Services Canada, 1991). The report noted, at 75, that "extension of the donor philosophy would mean that genetic material could not be sold, and donors would not have commercial interest in products developed using their tissues"... "in all cases, (it is critical that) individuals have control over the use of their tissues, including use in research or in the development of commercial products."

26 *Supra,* note 3, at 252.

27 L.B. Andrews, "My Body, My Property" (1986) 16:5 Hastings Center Report 28-38.

28 Discussion of intellectual property rights such as patents and copyrights of genetic material and cell lines are necessarily beyond the scope of this work as they belong to the legislative jurisdiction of the Federal Parliament. *Constitution Act 1867*, ss. 91(22), 91(23).

treatment. For close to seven years Mr. Moore gave samples of blood, skin, bone-marrow-aspirate and sperm during follow-up visits, which he believed to be for the purpose of monitoring his condition. Without his knowledge or consent, his cells, which contained unique and rare properties, were used to develop a cell line that was developed into a number of new pharmaceutical products by his doctor and another researcher. Patent rights for the cell line, tellingly christened "Mo", and its derivative products were assigned to the University. Licensing agreements with two corporations resulted in the successful mass marketing of these products to the extent that, by 1990, the cell line was expected to gross over $3 billion. Moore sued the University, the researchers, and the two pharmaceutical firms on thirteen different causes of action, including conversion of his property, lack of informed consent, breach of fiduciary duty, fraud and deceit and unjust enrichment.[29]

Although the trial court dismissed the action on the basis that the plaintiff had not established a cause of action for conversion, the California Court of Appeal reversed the judgment for dismissal and concluded that Moore had an action for conversion, based upon the ownership of his cancerous cells, which continued to belong to him even after their removal from his body.[30] The Court found that "no public policy has ever been established, nor is there any statutory authority, against a property interest in one's own body", property being liberally defined as an "ultimate right of control".[31] According to the court, consent to surgery and to the use of his cells for research purposes did not constitute consent to the commercial exploitation of his tissue.[32]

The California Supreme Court, however, overruled the appellate court's finding of a proprietary interest in Moore's cells and granted him relief based only upon the doctor's breach of their "fiduciary duty to disclose facts material to the patient's consent, or alternatively, on the performance of medical procedures without first having obtained the patient's informed consent".[33] The rejection of Moore's argument of proprietary interest in the patented cell-line and derivative products was based on the grounds that patents are granted to reward 'inventive effort' and not for the discovery of 'naturally occurring raw

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29 *Moore*, *supra*, note 9 at 498-99. *Black's Law Dictionary* , *supra*, note 2, defines conversion of property as follows:

> "An unauthorized assumption and exercise of the right of ownership over goods or personal chattel belonging to another, to the alteration of their condition or the exclusion of the owner's rights. Any unauthorized act which deprives an owner of his property permanently or for an indefinite time."

30 *Ibid.*, at 499. The same court concluded in 1993 that a dead man "had an interest in the nature of ownership, to the extent that he had decision-making authority as to the use of his sperm for reproduction". Before committing suicide, he deposited 15 vials of sperm to be frozen and had signed documents allowing the sperm bank to release them to his girlfriend. Similar provisions were found in his will and were vigorously contested in probate court by his children by a first marriage. The decision is currently under appeal. *Hecht* v. *Superior Court of California*, *supra*, note 7.

31 *Ibid.*, at 504-05.

32 *Ibid.*, at 510.

33 *Moore*, *supra*, note 9, at 150.

materials'.[34] The lack of precedent was seen as a hindrance. Policy considerations, which traditionally belong to the legislature's domain, led to the court's reluctance to address the property issue and to skirt around it by basing their finding in Moore's favour upon other, much less controversial, grounds.[35]

The *Moore* decision was considered by the United States District Court in *Miles, Inc. v. Scripps Clinic and Research Foundation.*[36] In this case, the court was addressing the "ownership" of a monoclonal antibody that was used to create a substance that permitted a hemophiliac's blood to clot and the cell line that was subsequently developed. The plaintiff made a claim in conversion arguing that the claim was not as to the cell line itself but rather to the "right to commercialize" the cell line that had been converted by the defendants.

The court agreed that "the property" at issue was the intangible right to commercialize the cell line, not the cell line itself.[37] The court acknowledged that even though it would be "possible to own a right to 'commercialization'... no cause of action for conversion has been recognized under the California Law for the alleged conversion of a right to commercialize cell lines. Instead, the intangible property right is one not protected by a conversion cause of action."[38] For policy reasons similar to those advanced in *Moore*, the court refused to expand the conversion cause of action.

The basic issue raised in *Moore* and *Miles*, as to whether or not a person has a proprietary interest in and hence a right to exploit commercially his or her body tissue, has yet to be definitively resolved in Canada. In the meantime, however, this case has generated much reflection and discussion in the legal community as to which legal framework will best strike the delicate balance between the rights of individuals as sources (or "suppliers") of biological material[39] and the rights of researchers and corporations ("users") to exploit such

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34 *Ibid.*, at 160.

35 In particular, the court held that the doctrines of informed consent and fiduciary duty were sufficient to give the plaintiff relief. *Ibid.*, at 163. For an analysis of the impact of the *Moore* case on Canadian and American patent law and on tissue/organ donation legislation see I. Jane Churchill, "Patenting Humanity: The Development of Property Rights in the Human Body and the Subsequent Evolution of Patentability of Living Things" (1994) 8 Intellectual Property Journal 249.

36 810 F. Supp. 1091 (S. D. Cal. 1993)

37 *Ibid.*, at 1094.

38 *Ibid.*, at 1095.

39 Be they living patients, research subjects or deceased persons. For an earlier discussion of this issue see Bernard M. Dickens, "The Control of Living Body Materials" (1977) 27 University of Toronto Law Journal 142. With advances in biotechnology, note that the issues raised in *Moore* are not an isolated instance. See *Potts v. Genentech* (unreported) (Nov 1988) Santa Clara County 67 0331 (Cal Sup. Ct.) where a female patient claimed that her blood, placenta and umbilical cord were, without her knowledge or consent, transferred from a hospital to a California biotechnology company to develop an rDNA drug (TPA) which has since been patented and is now licensed in Canada for use in dissolving blood clots after heart attacks as noted in Jennifer Horton, "A Personhood Analysis of Property Rights in the Human Body" (1995) 11(2) Canadian Intellectual Property Review 213 at 225.

material not only to develop new and beneficial therapies but also to reap profits. A legal response however, requires consideration and debate on the controversial, underlying policy issues.

3. POLICY CONSIDERATIONS

Policy considerations surrounding the issue of the legal status of human cells and tissue revolve primarily around two poles of debate: (i) the persons versus property debate; and (ii) the sale versus gift debate.

(a) PERSON VERSUS PROPERTY DEBATE

Perceived violations of human dignity are at the core of the arguments against applying a legal conception of property rights to human tissue. Rooted in the Judeo-Christian tradition, which believes that humans were created in God's image, there is much reluctance to adopt a legal framework that could lead to the commodification and, in a sense, the cheapening of human life. It could be argued that a human being is more than the sum total of its basic physical components and that there should be no moral aversion towards adopting certain incidents of property to replenishable or regenerative tissue once it is separated from the body. While common law jurisdictions grapple with the implications of adopting a property approach with regard to human genetic material, it is noteworthy that the new Civil Code of Quebec has aligned itself with the personal approach, which provides that questions with regard to the disposition of all human substances, cells, and tissues fall under the rules of the law of persons. Consent is required for all uses of such materials including surplus materials remaining after routine medical care.[40]

In 1993, the *Royal Commission on New Reproductive Technologies* took a strong position against the commercialization of human reproduction. In their report entitled *Proceed With Care*, the commissioners wrote:[41]

> In our view, no profit should be made from the selling of any reproductive material, including eggs, sperm or zygotes/embryos, because of its ultimately dehumanizing effects.

In spite of the above concerns, several strong arguments can be advanced in support of the recognition of property rights in human tissue.[42] Indeed, those who profess a moral aversion to the commodification or commercialization of the human body and its components may have lost sight of the fundamental modern legal concept of property, which does not refer necessarily to physical commodities sold or traded in the marketplace, but rather to "rights of control and domination over both tangible and intangible things or spheres of

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40 Art. 22 C.C.Q.

41 Royal Commission on New Reproductive Technologies, *Proceed with Care*, Vol. 1, (Ottawa: Minister of Government Services, 1993) at 447 (hereinafter RCNRT, Vol. 1) at 447.

42 Andrews, *supra*, note 27.

activity".[43] If property rights are to be viewed in terms of control over one's corporeal self and one's bodily products, then personal dignity may thus be enhanced rather than diminished.

It has been suggested that property rights in one's own tissue would provide a morally acceptable result by giving effect to notions of equity and fairness as well as by preventing unjust enrichment.[44] Similarly, denying the source of the raw material an equitable share of the profits derived from that biological matter may be viewed as unjust. Furthermore, such rights might contribute to the preservation of the crucial trust between patients and the medical profession by obviating the fear of profiteering by unscrupulous physicians.

A Canadian legal scholar has presented a strong case favouring that:[45]

> Property law, including such incidents as bailment of goods and liability for conversion, affords those who directly procure materials for transplantation, specifically the intermediate handlers and the medical staff serving the intended recipient, the knowledge that they are accountable to the donor for their use and misuse of that material. Those who control property can lawfully direct its use but also its return or deliberate destruction. However, the principle remains that materials separated from the body cannot be used except in accordance with either the donor's pre-release directions or subsequent adequately informed consent.... If statutory or regulatory provisions regarding human...research do not ensure exclusive control over the materials and it is not explicitly stated in an agreement, then this exclusivity nevertheless arises as an incident of property law.

The other ground for policy debate revolves around whether one may benefit financially from the sale of body materials or whether one must give them up gratuitously.

(b) Sale Versus Gift Debate

Canadian legislation has generally promoted a philosophy of altruistic donation with regard to organ and tissue donation. Arguments in favour of the gift ethic tend to emphasize the respect of the individual's choices and wishes, particularly after death, and respect for the human body or corpse. In 1992, the Law Reform Commission of Canada made several recommendations, regarding organ transplantation, to the same effect[46] and most recently, the new Civil Code of Quebec has enshrined the principle of gratuitous donation.[47] Although we

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43 Litman and Robertson, *supra*, note 3, at 243.

44 Andrews, *supra*, note 27.

45 B.M. Dickens, "Living Tissue and Organ Donors and Property Law: More on *Moore*" (1992) 8:73 Journal of Contemporary Health Law and Policy 73 at 90.

46 Law Reform Commission of Canada, *Procurement and Transfer of Human Tissues and Organs* (Working Paper 66) (Ottawa: Minister of Supply and Services Canada, 1992) at 67 to 69 (hereinafter LRCC, *Procurement and Transfer of Human Tissues and Organs*), Recommendations 2 and 11, at 171-72 and 184.

47 Art. 25 C.C.Q.

will examine all applicable legislation in Section C, it is of note that the relevant Ontario statute is entitled the *Human Tissue Gift Act*.[48]

The commercial/gift debate is where arguments against property rights tend to prevail. The most persuasive arguments against the recognition of such rights is the potential for adverse effects on the supply of organs and tissues available for transplantation and research. Predictions of decreases in the number of organs freely donated, of rises in the number of "inferior" specimens, of competitive bidding between physicians for limited resources, and, of financial pressure on the disadvantaged to sell their tissue are but a few of the spectres brandished about by advocates of the gift ethic.[49] The effect of patients and research subjects holding out for higher prices for their biological matter is similarly dreaded by the medical community, which predicts a rise in transaction costs between the "owner" and physician/researcher that would eventually be passed on through the health care system to the Canadian taxpayer. In addition, more expensive pharmaceutical or medical research would in all likelihood lead to higher costs with regard to drugs, treatments, and insurance for the consumer.

Interestingly, it has been suggested that the elimination of commercial transactions on donated organs and tissue does not depend on the denial of property rights. Indeed, denial of property rights may itself lead to commercial exploitation in the regulation of tissue and organ transfers. Recognition of living donors' property rights may forestall the emergence of an unsavory and exploitative growth of payments for services associated with acquiring tissues and organs. If living donors' property rights exist, then subsequent handlers may fear liability for conversion.[50]

A proposed alternative to the inter vivos sale of tissue and organs is a type of futures market, where rights to harvest a person's organs upon death are purchased during the individuals lifetime.[51] Such a position would take the sales approach (and the human person) to its ultimate "reification".

Despite these diverse and often contradicting policy considerations, legislatures have enacted statutes that are relevant and apply to the issue of property rights in human bodies and tissue, albeit indirectly and sporadically.

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48 R.S.O. 1990, c. H.19 (emphasis added).

49 See Barry Hoffmaster, "Between the Sacred and the Profane: Bodies, Property, and Patents in the *Moore* Case" (1992) 7 Intellectual Property Journal 115-148 at 134-135, who recalls the policy arguments raised by the *Moore* case. See also, T.H. Murray, "Gifts of the Body and the Needs of Strangers", (1987) Hastings Center Report 30.

50 Dickens, *supra*, note 45, at 92.

51 Henry Hansmann, "The Economics and Ethics of Markets for Human Organs" (1989) 14:1 Journal of Health Politics, Policy and Law 57-85.

4. CURRENT PRACTICES AND LEGAL FRAMEWORK

Human tissue, whether it is banked, used in research, or used in the production of biotechnological and pharmaceutical products, is provided by two distinct sources: dead persons or living persons. These sources raise different philosophical, ethical and legal problems. Ontario's current legislative framework reflects this duality and, accordingly, relevant statutes with regard to dead and living bodies or their constituent parts will be examined separately.

(a) THE DEAD BODY

Questions of property rights in human tissue have most often arisen in circumstances involving corpses. Rooted in religious beliefs and traditions, the common law has long held that, in order to preserve the dignity of the deceased, there can be no property in a dead body.

Three Ontario statutes are relevant to these situations. First, the *Anatomy Act*[52] allows unclaimed bodies to be used for anatomical dissection at medical schools. The language of the statute refers to a body being "under the control" of a local inspector and the statute makes no mention of any sort of property interest being transferred with the corpse. Second, the *Coroners Act*[53] outlines the circumstances in which a coroner can take possession of a body for investigative purposes and provides for the person performing a *post mortem* examination to extract the pituitary gland for use in the treatment of people affected by growth hormone deficiency.[54] While explicit consent by the deceased or his or her family is not required to remove the gland, extraction is not permitted if any objections are raised.[55] The third relevant statute, the *Human Tissue Gift Act,*[56] provides in section 5 that, in cases where the deceased had not previously consented to donating tissue,[57] a spouse, relative or another person "lawfully in possession of the body" may consent "to the body or the part or parts thereof specified in the consent being used for therapeutic purposes, medical education or scientific research".[58] Thus, while none of these laws create any substantial property rights in corpses, all three do appear to acknowledge the existence of a limited possessory interest in human bodies.

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52 R.S.O. 1990, c. A.21, s. 4.

53 R.S.O. 1990, c. C.37.

54 *Ibid.*, s. 29(1).

55 *Ibid.*, s. 29(2).

56 R.S.O. 1990, c. H.20.

57 *Ibid.* Defined at s. 1 as including "an organ, but does not include any skin, bone, blood, blood constituents or other tissue that is replaceable by natural processes of repair".

58 *Ibid.*, s. 5(2).

Often qualified as a quasi-property interest, the courts have also vested executors and families with possessory rights for the limited purpose of discharging their duties of burying or disposing of a body.[59] In the case of *Waldman* v. *Melville (City)*, a Saskatchewan court extended the executor's right to custody and possession of a corpse beyond the time of burial. The facts of the case revolved around an application by a sibling to exhume and relocate a body in opposition to the executor's wishes and what the court determined to be her continuing right to determine the place and manner of burial.[60]

Some courts have also given effect to a quasi-property conception of corpses by allowing spouses or next of kin to sue for damages when wronged by interference to the body. In many of these cases, however, damages are awarded as compensation for emotional distress caused to the bereaved.[61] Instances of interference have included negligent handling or transporting of dead bodies,[62] the withholding of a body for payment of funeral expenses[63] and mutilation of the deceased in the course of an unauthorized autopsy.[64]

In a bizarre turn-of-the-century Australian case, the High Court indicated that although a corpse is not normally a subject of property, it can become so "when a person has by the lawful exercise of work or skill so dealt with a body in that person's lawful possession that it has acquired some attributes differentiating it from a mere corpse awaiting burial, then that person has a right to retain possession of it".[65] In adding that a portion of a human body is capable by law of becoming the subject of property, the court anticipated by nearly eighty years situations like that in the *Moore* case, arising in the field of biotechnology where human effort and intelligence are being used and applied to transform human tissue into new products that may or may not be qualified as property.

In 1992, the Law Reform Commission of Canada recommended the following within the context of Parliament's jurisdiction in matters relative to the criminal law:[66]

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59 See *Edmonds* v. *Armstrong Funeral Home*, *supra,* note 8; *Philipps* v. *Montreal General Hospital*, *supra,* note 8.

60 [1990] 65 D.L.R. (4th) 154 (Sask. Q.B.).

61 LRCC, *Procurement and Transfer of Human Tissues and Organs*, *supra*, note 46, at 67-69.

62 *Miner* v. *Canadian Pacific R.W. Co.*, (1911) 18 W.L.R. 476 (Alta S.C.).

63 *Hunter* v. *Hunter*, [1930] 4 D.L.R. 255 (Ont. S.C.).

64 See *Edmonds* v. *Armstrong Funeral Home*, *supra,* note 8.

65 *Doodeward* v. *Spence*, (1908) 6 C.L.R. 406 at 414. The case involved a side-show operator who had been exhibiting a set of Siamese twins preserved in alcohol who sued for the return of his property when they were impounded be a public official.

66 *Supra*, note 46, at 187.

> 12. Human remains or bodily substances that are in one's lawful possession or that have been lawfully procured and transformed by skill and labour...should be considered proprietary objects that fall within criminal law protections against theft.

In the report of the Commission, "broader concepts of property" and the fact that "[m]odern legal analysis no longer automatically equates property with commerce" were invoked as reasons to adopt a restricted property law regime and protections, in the context of the criminal law with respect to certain categories of human remains.[67] Nevertheless, the thornier question as to the legal classification of transformed or transformable human tissue extracted from living persons remains.

(b) The Living Body and its Constituent Parts

Medical developments of the last half century have raised novel issues in proprietary rights in living bodies. In this section we shall briefly overview some of the approaches of the more "traditional" tissue banks as well as the more recent DNA, cell line, and data banks. Statutes and case law relevant to the issue of proprietary interest in human tissue will then be discussed.

Currently, blood banking is the most common tissue banking service, with approximately 900 blood banks in Canada.[68] While sales of blood and derivative products are not specifically prohibited, most blood is donated gratuitously, in stark contrast to the American market system, which pays many of its donors. Canadian breast milk banks also promote the concept of donation for altruistic purposes.[69] However, men who provide sperm to be frozen and banked for later use in artificial insemination normally receive a nominal fee to compensate them for the inconvenience, rather than as a financial incentive.[70] Other organs

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67 *Ibid.*, at 188.

68 *Ibid.*, at 24.

69 *Ibid.*, at 24 and 26.

70 RCNRT, Vol. 1, *supra*, note 41, at 448. Paid sperm donors are normally viewed as providing a service rather than a product. It is interesting to note, however, that a woman in British Columbia, who contracted the HIV virus after being artificially inseminated, sued her physician for providing her with damaged goods under the warranty of that province's *Sale of Goods Act*. Her claim on that ground was dismissed at trial and the ruling was confirmed by the Court of Appeal. See *Neuzen* v. *Korn*, 29 B.C.A.C. 1, 48 W.A.C. 1 (June 21, 1993). See also Health Canada, Government of Canada's July 27 1995 Communiqué where Health Minister Diane Marleau urged a voluntary moratorium on nine reproductive technologies - including sex selection techniques, commercial contracts for surrogate motherhood and the buying and selling of eggs, sperm and embryos. Marleau indicated that these technologies threaten human dignity, present serious social, ethical and health risks and treat reproduction, women and children as commodities. To encourage compliance, no federal department or granting agency will provide funding to individuals or organizations engaging in such practices. This moratorium constitutes the government's response to the Royal Commission on New Reproductive Technologies who recommended that sex selection, commercial surrogacy contracts and embryo cloning be outlawed and that a licensing body to strictly regulate all other reproductive technologies be instituted.

and tissues currently being harvested, banked, and transplanted in Canada include eyes, skin, bones and bone marrow.[71]

Biotechnological and genetic research have recently added yet another dimension to the difficulties raised by the question of the legal characterization of human body parts once they are detached from the individual. Where once a whole organ was removed from one person and transferred to and for the benefit of another, today small amounts of tissue, regenerative or not, can be cultured and reproduced, created into a cell line which in turn can be developed into a myriad of new therapeutic and pharmaceutical products with the potential to benefit thousands.

These scientific advances are, however, a double-edged sword pitting against each other philanthropic and humanitarian urges with drives for new discoveries and breakthroughs, fame and fortune. Similarly, awareness of the profit-making potential of biotechnological research being performed on human tissue has the potential to seriously erode patient-physician trust. From the patient's perspective, the fact that each and every cell, no matter what its point of origin, can be genetically read, may constitute a serious threat to his or her bodily integrity and privacy.[72]

With a viability period of close to twenty years for frozen human cellular tissues[73] and DNA's potentially indefinite stability, banking has found a large number of applications in both clinical and research contexts. Amongst other things, it facilitates diagnostic work by allowing comparison of cells suspected of having genetic abnormality with previously banked cells already known to be atypical.[74] Banking, such as that used in the context of Canada's predictive testing program for Huntington disease, permits DNA to be extracted from tissues of living or deceased family members for comparative diagnostic testing.[75] Considering the breadth of the Human Genome Project, which has as its objective the mapping and sequencing of the entire human genome, diagnostic and predictive tests will inevitably be developed for other genetically-related conditions (both monogenic and multifactorial). Further, cell and DNA banking will in all likelihood become an important tool in the health care of Canadians.[76]

Whether for research or clinical service purposes, depositors generally retain some measure of control over what will happen to their samples after they have been banked.[77]

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71 LRCC, *Procurement and Transfer of Human Tissues and Organs*, *supra,* note 46, at 22 to 27.

72 See *infra,* ch. 9.

73 LRCC, *Procurement and Transfer of Human Tissues and Organs, supra*, note 46, at 25.

74 *Ibid.*, at 25.

75 *Ibid.*, at 25-26.

76 *Ibid.*, at 26.

77 In J. Hall, J. Hamerton, D. Hoar, R. Korneluk, P. Ray, D. Rosenblatt and S. Wood, "Policy Statement Concerning DNA Banking and Molecular Genetic Diagnosis", (1991) 14 *Clin. Invest. Med* 363 at 365, the

Anonymous studies for epidemiological or public health surveillance purposes are usually excepted from the routine information and consent requirements.[78] Where samples are being banked for research, two approaches are possible. The first would be to inform depositors of the institutional policies, that is, of the possibility that their samples will be used in research other than the specific research protocol for which they were provided. Further, they would have a right to know of any possible commercial benefit that might inure to the researcher from studying their stored DNA and of the banks policy regarding who may share in any such profits. The second approach envisages participation of a research subject or a patient in DNA banking as governed by the gift principle and avoids language such as deposit or property. The "gift" however, would be subject to providing the donor with options to be banked or not, to limit uses (specific research or other clinical uses), to limit access, and to be followed-up or not subject to the donor informing the bank of any change of address or continuing interest in being banked. The notions of an expanded informed consent and of respect for bodily integrity and personal values underlie this approach.[79] In this manner, the donor would maintain control over his DNA samples while any intellectual property interests would rest with the researcher or institution. Eventual profits (if any) would be shared with the public and the scientific community at large.[80]

One issue that is rarely raised in any discussion of DNA banking is that of access by family members during a person's lifetime or after that person's death. A recent 1995 report by WHO advisors recommends that "[a]ll blood relatives should have access to stored DNA for purposes of learning their own genetic status, but not for purposes of learning the donor's status" and "[p]otentially valuable tissue specimens in departments of pathology that could be useful to families in the future should be saved and should be available".[81] Quebec legislation

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Canadian College of Medical Geneticists has indicated that the disposal, storage, or continued use of DNA, once in the hands of a diagnostic service, is a matter of local institutional policy and the transfer to other labs for appropriate diagnostic testing is subject to the same condition. See also Jean E. McEwen and Philip R. Reilly "A Survey of DNA Diagnostic Laboratories Regarding DNA Banking" (1995) 56 *Am J. Hum. Genet.* 1477 at 1484. See finally the recent proposal of Annas et al. *supra* , note 23. Their Proposed Genetic Privacy Act provides the sample source with a right of control in so far as he must agree to the transfer of his material to another researcher or may require the destruction or the return of his DNA sample (section 162).

78 Medical Research Council of Canada, *Guidelines on Research Involving Human Subjects* , (Ottawa: Minister of Supply and Services Canada,1987) at 26. Note also that the Science Council of Canada, *supra*, note 25 at 73 provides that participants understand the potential uses of the banked material and specify the uses to which they consent.

79 This approach was first proposed by B.M. Knoppers, C.M. Laberge, "DNA Sampling and Informed Consent" (1989) 140 *Can Med Ass J* 1023-28.

80 See Réseau de génétique humaine appliquée du Fonds de recherche en santé du Québec, "Énonçé de principes: Médecine génétique et recherche génomique". (Translation "Statement of Principles: Genetic Medicine and Genome Research") (1995) *La Recherche en santé* 8 (June) 30-34. See also the NIH-EISI Working Group's paper of March 1995, *supra*, note 24, and accompanying text.

81 D.C. Wertz, K. Berg, J.C. Fletcher, V. Boulyjenkov, *Guidelines on Ethical Issues in Medical Genetics and the Provision of Genetic Services*, (1995) (Geneva: WHO) at 70-71. (Forthcoming).

has mandated family access at least after death, and this in spite of any former refusal by the deceased.[82]

Banking also occurs after DNA identification testing for filial[83] or forensic purposes, the latter not being a subject under provincial jurisdiction. Military DNA banks, such as that recently set up in the United States, are used for identification purposes of soldiers who die in combat.[84] This form of banking does not involve genetic testing for disease but can involve the indefinite storage of information derived from DNA.

The most common facilities however are DNA forensic banks that focus on the uses of DNA information in a criminal law context. A recent American survey[85] indicated that while many crime laboratories in that country planned to destroy samples drawn from convicted offenders where the conviction that supplied the basis for drawing the sample was overturned, several others, in the absence of relevant legislation, intended to retain the material already in their possession.[86] The possibility of Canadian genetic profiles of convicted criminals and of special "DNA warrants" was examined by the federal Ministry of Justice[87] and was passed by the House of Commons on June 22, 1995 (Bill 104). Clearly, the question of control, dominion or ownership of tissues, and cells generally, however banked, needs to be addressed.

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82 See *Act Respecting Health Services and Social Services,* S.Q. 1991, c. 42, art 23, which provides, in part, that "persons related by blood to a deceased user may be given communication of information contained in his record to the extent that such communication is necessary to verify the existence of a genetic or hereditary disease"; most European jurisdictions follow this approach, see also B.M. Knoppers and R. Chadwick, "The Human Genome Project: Under an International Ethical Microscope" (1994) 265 Science 2035.

83 See *infra*, ch. 5.

84 "DNA Dog Tag or Genetic ID?" (June 22,1992) Time at 16-17; W. Melillo, "Genetic Record Will Help Identify Unknown Soldiers" (January 14, 1992) The Washington Post.

85 Jean E. McEwen, "Forensic DNA Data Banking by State Crime Laboratories" (1995) 56 *Am. J. Hum. Genet.* 1487.

86 *Ibid.,* at 1490-1. The need for retesting at a later date when newer PCR-based technologies come on line in order to avoid rendering the data bank obsolete, was cited as the primary reason for retaining samples. It is significant to note however, the while the National Academy of Sciences (National Research Council, Commission on Life Science) 1992 report acknowledged the practical desirability of retaining samples for short periods until the technology becomes more stable, it recommended that once this has occurred and the data banks are better established, samples should be promptly destroyed after they have been analyzed. The finding that laboratories plan to retain samples indefinitely after they have analyzed them for their data banks raises concerns relating not only to property issues but to the security and confidentiality of this highly personal genetic information.

87 *Obtaining and Banking DNA Forensic Evidence*, Consultation paper, Department of Justice Canada (September 21, 1994). It should be noted however, that this form of DNA banking concerns genetic identification testing and not medical testing for genetic conditions.

At this time, statutory sources provide scarce guidance to the multitude of questions and problems raised by the advent of these new scientific realities. Indeed, section 10 of Ontario's *Human Tissue Gift Act* specifies as follows:

> 10. No person shall buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any tissue for a transplant, or any body or part or parts thereof other than blood or a blood constituent, for therapeutic purposes, medical education or scientific research, and any such dealing is invalid as being contrary to public policy.

The general thrust of this section indicates that human tissue is not to be sold. Since section 1 of the Act, as we have seen, defines tissue restrictively and excludes from its ambit not just blood but other replenishable or regenerating substances as well, it can be inferred that these are not subject to the sales prohibition. Logically, it would seem that no property rights can exist in such tissue since living tissue is statutorily barred from being disposed of—a fundamental right of property.

However, closer inspection of section 10 indicates that its general thrust is uncertain.[88] While the section does allow blood or blood constituents to be traded for valuable consideration, it is unclear whether any of the regenerative substances outlined in section 1 would nonetheless fall within the meaning of "bodily parts" of section 10 and if so, under what circumstances. The Law Reform Commission of Canada notes that one jurisdiction in the United States has exempted cell lines from its prohibition on the sale of tissue, raising the query of whether the provincial tissue sales bans are intended to apply to cellular or subcellular entities.[89] Further, prohibition on dealing in tissue or body parts for valuable consideration is incomplete in that section 10 is limited to certain specified purposes—therapy, medical, education and scientific research.[90]

Modifications to this act have been proposed by the Uniform Law Conference of Canada but have yet to be brought into effect in Ontario.[91] Recommendations include

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88 For an alternative interpretation see B.M. Dickens, supra, note 39, at 168 where he argues that this statute may not cover bartering for insurance arrangements and thus may be interpreted as barring only trading in human tissue for valuable consideration. Dickens elsewhere (see "The Ectogenic Human Being: A Problem Child of Our Time (1980) *U. W. O. L. Rev.* 241 at 257) suggests that if the transfer of human materials is regarded as a service rather than as a sale, it may be possible to argue that the statute's prohibition on commercial transactions does not apply, thus circumventing it entirely.

89 LRCC, *Procurement and Transfer of Human Tissues and Organs*, *supra*, note 46 at 135. See also Jennifer Horton, *supra*, note 39 at 222 who poses the same query.

90 J. Horton, *ibid.*, posits the query: "Since the HGTA only prohibits sales for "therapeutic purposes, medical education, or scientific research" do they proscribe sales for more strictly commercial uses such as cosmetics?" at 222. Further, see R.W.. Marusyk and M. Swain, *supra*, note 1 at 363 who pose further queries on the interpretation of S. 10: do property rights exist in one's own blood or do they only spring into existence when valuable consideration is exchanged? If no property rights exist before valuable consideration is exchanged, could this exchange not be viewed as payment for services rendered?

91 *Uniform Tissue Donation Act* (1989), in Uniform Law Conference of Canada, *Consolidation of Uniform Acts* (1990 Supp.) 22-1.

redefining tissue as a part of a living or dead body but exclude spermatozoa, ova, embryos, foetuses, blood and blood constituents from its definition.[92] Sales would furthermore be prohibited for therapeutic, medical education and scientific purposes and commerce in human tissue would become a summary conviction offence, punishable by a maximum fine of $100,000 and/or a maximum one year prison term.[93]

In a more oblique manner, Ontario's *Health Care Consent Act, 1996*[94] may also be relevant in cases similar to *Moore*. Section 11(1) of the Act requires four basic elements for proper consent to be given before treatment begins: consent must first and foremost relate to treatment; it must also be informed; given voluntarily; and, finally, must not have been obtained through misrepresentation or fraud. Section 11(2) and (3) elaborates upon the notion of informed consent:

> 11.—(2) A consent to treatment is informed if, before giving it,
>
> (a) the person received the information about the matters set out in subsection (3) that a reasonable person in the same circumstances would require in order to make a decision about the treatment; and
>
> (b) the person received responses to his or her requests for additional information about those matters.
>
> (3) The matters referred to in subsection (2) are:
>
> 1. The nature of the treatment.
>
> 2. The expected benefits of the treatment.
>
> 3. The material risks of the treatment.
>
> 4. The material side effects of the treatment.
>
> 5. Alternative courses of action.
>
> 6. The likely consequences of not having the treatment.

If one applies the facts of the *Moore* case to a situation of surgical excision or other form of medical tissue removal, it is striking that the question of use and/or disposal of such tissue is not strictly legally required in physician-patient discussions. At first glance then, a medical doctor could thus fulfil his or her legal obligation to inform the patient of therapeutic benefits and drawbacks of a particular course of treatment while concealing personal,

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92 *Ibid.*, s. 1.

93 *Ibid.*, s. 15.

94 S.O. 1996, c. 2, Sched. A.

professional, or financial stakes in the matter. In contrast, article 22 of the new Civil Code of Quebec states that:

> 22. A part of the body, whether an organ, tissue or other substance, removed from a person as part of the care he receives may, *with his consent or that of the person qualified to give consent for him,* be used for purposes of research [emphasis added].

In a common law context, it could nonetheless be argued that the holding of the Supreme Court in *McInerney* v. *MacDonald*[95] would preclude such behaviour. In that case, the court reaffirmed the fiduciary nature of the physician-patient relationship and emphasized that "trust and confidence" are its main touchstones.[96] This situation, however, does mandate that a closer look be taken at such conflicts of interest, particularly within the context of current Canadian medical and research practices.

There is little Canadian case law that addresses proprietary interests in human tissue extracted from living bodies. The closest the courts have come to dealing with this issue is in the *Dyment*[97] case, in which the Supreme Court held that the non-consensual use of a medical blood sample was a violation of section 8 (unreasonable search and seizure) of the *Canadian Charter of Rights and Freedoms.*[98] Laforest J., while declining to decide the case on the basis of property rights considerations, stated that "it would not be far-fetched to do so".[99] In the pre-Charter case of *Capostinsky* v. *Olsen*, a court in British Columbia found that individuals do have a property interest in their blood.[100] The facts in that instance revolved around the Royal Canadian Mounted Police's seizure (with a warrant) of blood samples taken from the unconscious plaintiff after a motor vehicle accident. The plaintiff later sued in an action in replevin pursuant to the British Columbia *Recovery of Goods Act,* for the return of the samples, which he alleged were his property.[101]

In the United States, a few cases aside from *Moore* have examined questions of proprietary interests in human tissue and have distinguished between living parts of the body and parts that were naturally detached or abandoned. In the case of *R. v. Williams*, Melnick J, after taking judicial notice that DNA "is the essential building block of the human cell...and is

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95 [1992] 2 S.C.R. 138.

96 *Ibid.,* at 149.

97 *R.* v. *Dyment,* [1988] 2 S.C.R. 417.

98 Part I of the *Constitution Act 1982*, being schedule B of the *Canada Act 1982* (U.K.), 1982, c. 11.

99 *Supra*, note 97 at 432. See also *R.* v. *Dersch*, [1993] 3 S.C.R. 768 and *E. v. Colarusso* (1994) 87 C. C. C. (3d) 193 where the *Dyment* approach was reiterated.

100 (1981) 27 B.C.L.R. 97 (BCSC).

101 *Ibid.* An action in replevin is similar to that of an action in conversion. It is defined in *Black's Law Dictionary* , *supra*, note 2, as "an action whereby the owner or person entitled to repossession of goods or chattel may recover those goods or chattel from one who has wrongfully distrained or taken or who wrongfully detains such goods or chattels".

thus a very personal "thing",[102] concluded that "the duty to respect the dignity and the privacy of a person must take precedence...when that seizure is of living body parts for the purpose of DNA analysis. In that I include blood, saliva and hair that would need to be plucked from the body. I do not include abandoned parts".[103] In contrast, in *Venner* v. *State,*[104] a man who had ingested large quantities of a narcotic for the purpose of smuggling the drug into the United States, claimed a proprietary interest in his excrement, which customs agents seized as evidence. The court ruled that an individual could retain a property right in waste matter or other materials that are normally shed or excreted through natural processes or intentionally separated from the body.[105] In examining the second issue of abandonment, it was decided that a person must express an intent to retain ownership, possession or control of such biological waste, otherwise there is a presumption, based upon human experience, that the intent is to abandon the biological material in question. In another case, a woman who had been selling her plasma, which contained rare antibodies, to a hospital was sued by the Internal Revenue Service for not having declared the sums received as income. The court found that the money she had earned could be taxed either as a service or a product.[106]

As we have seen, the Canadian legal system appears to sanction the altruistic and gratuitous transfer of tissue, also known as the gift ethic. This legal framework, however, has been developed to address the medical advances of the past twenty years in the area of transplantation of whole organs from a healthy body to a diseased one and has not evolved with the new realities of biomedical research, which can manipulate human tissue in order potentially to benefit thousands of individuals with new pharmacological products. Nor do these laws take into account the fact that the DNA contained in every single human cell encodes each person's unique genetic characteristics and thus contains what may be viewed as highly sensitive and private information. At the same time, it must be borne in mind that cases such as *Moore* and the instances of one particular individual producing cells with such remarkable therapeutic properties are exceedingly rare. Cells, tissues, and DNA acquire uniqueness in the way they are combined to create an individual human being. Nor can we neglect the effect of the interaction of that person with a given environment and culture over time. Moreover, the eventual marketing of an ultimate product by industry involves years of research, development and investment. We must therefore not lose sight of the fact that once removed or separated from the body and placed in a petri dish or under a microscope, a piece of tissue or a strand of DNA loses most of what made it so special, particularly in the absence

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102 (1992) 76 C.C.C. (3d) 385 (B.C.S.C.) at 397.

103 *Ibid.*, at 409.

104 *Supra*, note 10.

105 This is the closest any American court has come to recognizing a property right in something that was previously a part of an individual's body, that is, by refusing to hold that no such property right exists. The Court noted that: "[i]t could not be said that a person has no property right in wastes or other material which were once a part of or contained within his body, but which normally are discarded after their separation from the body" at 626-627.

106 *United States* v. *Garber*, 589 F. 2d 843,848 (5th Cir.), *rev'd on other grounds*, 607 F. 2d 92 (5th Cir. 1979) (en banc).

of other information on the person. Keeping these considerations in mind, it is essential to the debate to weigh the various alternative legal approaches proposed for the qualification of the relationship existing between a person and his or her body parts.

5. ALTERNATIVE APPROACHES

In addressing the issues raised by the recognition of property rights in body parts, several interesting alternative legal approaches have been proposed. In this section we shall briefly consider the alternative approaches of quasi-property, of *sui generis* characterization, of extended informed consent, of rights of publicity as developed in intellectual property rights, of the right of commerciality, and finally, of a three-tiered legal structural approach.

As we have seen, much of the jurisprudence relating to dead bodies has allowed for a quasi-property analysis of survivors' limited[107] legal interest in their loved one's remains. In certain cases, regenerative body parts and products have been excluded from the general prohibition against alienation in return for consideration,[108] and have been endowed with strictly limited incidents of property. With regard to human genetic material, however, the quasi-property framework may not be quite so useful as it tends to straddle the fence between the proprietary and personal approaches and to dissemble the crucial and controversial policy choices at hand, in particular, the right to sell and profit from one's bodily tissue.[109]

Another approach, which resembles that of quasi-property, and which has also been applied in cases relating to dead bodies,[110] has been the characterization of certain objects as *sui generis* or unique. A *sui generis* interest need not have any pre-determined standard incidents of property but instead allows the law relating to particular categories of objects to be developed on a case by case or *ad hoc* basis.[111] Policy goals are viewed as central to the decision-making process and in determining which, if any, incidents of property should apply to biological matter. With regard to reproductive materials, it has been argued that the label of property should be avoided for symbolic and political reasons and that interests in the control and disposal of such biological matter should be described as *sui generis*.

A research paper of the *Royal Commission on New Reproductive Technologies* maintained that "a legislative scheme that characterizes reproductive materials as *sui generis*, but that does not reject property principles, affords courts latitude without evoking an

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107 A possessory interest for the purpose of disposal or burial only. See *Edmonds* v. *Armstrong Funeral Home*, *supra*, note 8; *Philipps* v. *Montreal General Hospital*, *supra*, note 8.

108 For instance, breast milk, blood, hair, semen, bone marrow and skin. See *supra*, note 70 on the federal government's call for a voluntary moratorium.

109 Litman and Robertson, *supra*, note 3, at 247.

110 *Philipps* v. *Montreal General Hospital*, *supra*, note 8.

111 Litman and Robertson, *supra*, note 3, at 247-248.

unwarranted and unnecessary emotional debate".[112] Yet, the indeterminate nature and inherent uncertainty of a *sui generis* approach is vulnerable in that it is an easy escape route for reluctant policy-makers. Furthermore, leaving difficult choices up to ad hoc judiciary decisions undermines the development and promotion of clear and comprehensive guidelines in this burgeoning area of the law.

Until recently, the common law has relied upon the principle of informed consent of the person and attendant damages to govern the non-consensual use of bodily tissue, rather than apply a property framework. However, if informed consent continues to be relied upon in medico-legal contexts, the concept will need to be expanded and refined since it currently "fails to require disclosure regarding what will happen to the patient's body parts once they have been removed from her body".[113] A person's right to self-determination encompasses a "dignitary interest in one's body and extracorporeal body parts" which includes the right to control what happens to excised tissue and cells, an interest wholly distinct and independent from property rights.[114] Currently, informed consent mandates that a physician seek and secure a patient's informed consent before surgery or any other course of medical treatment.[115] Although disclosure is required regarding what will happen to the patient during and after the operation, there is currently no legal requirement in Ontario to inform the patient of the fate of (or even provide choices concerning), the patient's tissues once they are removed.[116]

Under the influence of the *Moore* decision, it has been proposed that the doctrine of informed consent be extended to impose a duty upon the physician to disclose not only the risks and benefits associated with a certain medical treatment, "but also the proposed use, if any, of the patient's body parts".[117] Potential commercial gain would similarly have to be disclosed. Thus, it has been suggested: [118]

> If the doctor has a professional interest in the discarded material which affords the patient no therapeutic or diagnostic benefit, the patient's express consent should be sought beforehand lest

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112 *Ibid.*, at 268.

113 S.N. Perley, "From Control Over One's Body to Control Over One's Body Parts: Extending the Doctrine of Informed Consent" (1992) 67 N.Y.U. Law Review 335 at 337.

114 *Ibid.*

115 *Health Care Consent Act, 1996*, *supra*, note 94.

116 *Ibid.*, s. 11(2) and (3). For a discussion on the different remedies offered by informed consent and property claims to the transplantation donor see Dickens, *supra*, note 45, at 87-89. Also see Gerald Dworkin & Ian Kennedy, "Human Tissue: Rights in the Body and Its Parts" (1993) 1 Medical Law Review 291-319, at 306-314. Note that this is the Quebec approach, *supra*, note 40.

117 Perley, *supra*, note 113, at 337.

118 I. Davies, "Live Donation of Human Body Parts: A Case for Negotiability?" (1991) 59:2 Medico-Legal Journal 100 at 105.

abandonment of his property may appear to have been effectuated by the exercise of undue influence.

Additionally, while not a matter of provincial jurisdiction, it has been suggested that the *Patent Act* be amended in order to ensure proper informed consent. Such an amendment would require all patent applications involving the use of human material at any stage of the research to prove that proper informed consent was obtained for the use of that material. Therefore, all donors of human material would have to be disclosed in a patent application. Improper consent would still allow the patent application to proceed, but the patent office would inform donors of the non-consensual use of their tissue and thus give them the option of exercising their legal rights.[119] Irrespective of these latter unrealistic conditions, an expanded doctrine of informed consent could well meet current scientific needs in this area although respect for the inviolabilty and integrity of the person, which includes control over the disposal of one 's bodily material and information derived therefrom, must be subsumed within this framework.

Another interesting legal approach to the problems raised by property rights in one's bodily tissue, which was advanced in *Moore* and which merits consideration with regard to the protection of an individual's unique—and yet at the same time universal—genetic characteristics or heritage,[120] is the intellectual property notion of rights of publicity. In the cases of *Lugosi v. Universal Pictures*[121] and *Midler* v. *Ford Motor Co,*[122] Californian courts examined the protection of a person's unique image and physical attributes such as their voice, appearance, and personal features. In the *Lugosi* case, the question before the court was whether the persona of a film actor, a proprietary right, could be transmitted to his heirs. The court found that there did exist a right in an actor's name and likeness but that it did not survive the actor. However, in 1984, the California state legislature amended its Civil Code and enacted section 990, which permits the transmission of limited personality rights to legal heirs of the deceased for a period of fifty years. In other states, the right of publicity has been found to be descendible.[123] The Ford Motor Company was similarly sued by the singer and actress Bette Midler for using a "sound-a-like" or voice impersonator in a television commercial after Midler had refused to participate in a publicity campaign. In the context of a tenable property rights approach for genetic material, this alternative is unworkable as it is linked to the concept of a whole human being and not directly to the genetic and physical components of the body.[124]

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119 Marusyk and Swain, *supra*, note 1, at 379.

120 On the notion of genetic heritage, see B.M. Knoppers, *Human Dignity and Genetic Heritage*, (Ottawa: Law Reform Commission of Canada, 1991).

121 603 P. 2d 425 (1979) (Cal. Sup. Ct) (Hereinafter *Lugosi*).

122 849 F. 2d 460 (9th Cir. 1988).

123 See *Estate of Presley* v. *Russen,* 513 F. Supp 1339 (1981).

124 Marusyk & Swain, *supra*, note 1, at 357. Also see R.W. Marusyk & M.S. Swain, "An Alternative To Property Rights in Human Tissue" (1990) Sept./Oct. Hastings Center Report 12-15. See *Moore*, *supra*, note

The right of commerciality,[125] another approach, is a limited property right. Under this right, a person would have intangible rights in the commercial potential of his or her own body, which would arise only when the body is exploited for profit.[126] This would complement the quasi-property rights already recognized and would not vest an absolute right of possession in the physical object, that is, the human tissue. The right of commerciality would protect the value of one's body or its derivatives, prevent its misappropriation and the unjust enrichment of others, and place the individual in an equal bargaining position with researchers, medical institutes, and biotechnology corporations.[127] If this right presupposes that the excised tissue has been transformed by scientific technology and intensive labour, as suggested in the third tier of Marusyk and Swain's proposal below, then, to a limited extent, and in conjunction with an expanded informed consent framework, this approach may have merit.

The Law Reform Commission of Canada implicitly agrees with the notion that human tissue generates property rights only when in conjunction with high technology and recommended that the purchase or sale of human bodies, organs and other non-regenerative tissue be made a *Criminal Code* offence. At the same time it recommended that bodily substances "transformed by skill and labour into...processed and preserved tissue...should be considered proprietary objects that fall within criminal law protection against theft".[128]

In 1989, Marusyk and Swain proposed a three-tiered legal structure, which classifies different types of human substances, to accommodate property rights in new products created through the application of labour to human tissue. Their position was largely influenced by the California Court of Appeal's judgment in the *Moore* case but its overruling by the state's Supreme Court highlights the judiciary's reluctance to make such a delicate and controversial policy choice. The first level of their system looks at the human body as a whole, including the *persona*. The sum total of organs, tissues, and genetic material that create a unique individual would fall under the classification of property rights (including the right of publicity) as long as the parts remain within the person. Once a physical component is detached or removed from the body in a way that no longer serves the original possessor, it would fall into the second tier of the legal structure, which the authors have deemed to be *res nullius*. As such, the removed or excised tissue would become a corporal moveable owned by no one. Under this classification, ownership would be acquired by the first person who took possession of the tissue. In cases of transplantation, the legal system could deem those in

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9, at 508 where the court considered one's genetic material to be "far more profoundly the essence of one's uniqueness than a name or face." In Quebec, see art. 36(5) C.C.Q.

125 See Roy Hardiman, "Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue" (1986) 34 *U.C.L.A. Law Rev.* 206 at 258, 260-1. The right of commerciality, it is contended, would also preserve altruistic donation.

126 The right of commerciality would not apply to human tissue excised for pure non-profit research. Only if and when the research produced earnings from commercial application would the patient's rights be actionable.

127 Furthermore, the right of commerciality would be transferable, desirable and part of the decedent's estate.

128 LRCC, *Procurement and Transfer of Human Tissues and Organs*, *supra*, note 46, at 184, 187.

temporary possession of the tissue such as doctors as being possessors "in trust" until the transplant operation is completed. At the third level of cases, where tissue is removed permanently from a human body, such tissue would be characterized as *res communes omnium.* The authors maintain that, in order to preserve an ethic of humanitarianism and to prevent such tissue from becoming a marketable commodity, it should be characterized as a thing "that by natural law [is] the common property of all humans".[129] However, once intelligence, labour and technology have been applied to the tissue in order to transform it into something else, the final product would be susceptible of generating property rights, be they intellectual property or pure and private property.

If applied to the facts of the *Moore* case, this legal structure would have resulted in the plaintiff's spleen and other cells being deemed *res communes omnium* from the moment the splenectomy was completed and would have prevented him from claiming any proprietary rights or any remuneration based upon such rights. The doctors and the educational institution involved would, however, be rewarded for their investment of time, money and, most importantly, labour with (intellectual) property rights.[130]

6. CONCLUSION AND RECOMMENDATIONS FOR REFORM

As we have seen, the lack of guidance for particiapnts in the biotechnological field, that is, for patients, research subjects, physicians, researchers and corporations, presents difficulties and obstacles for all involved. Furthermore, considering the power imbalance between physicians/researchers and patients/participants, the clinical and research settings are not the proper fora for the "ad hoc negotiation" of such issues. The need for legislative intervention and guidance with regard to the legal characterization of human genetic material remains pressing. Whatever the policy solutions brought forward, they must necessarily create a delicate balance between respect for the individual human source and the promotion of scientific research that can benefit the community at large.

It is our view that a personal rights approach would protect individuals' interests in their bodies and constituent parts while alive, and enshrine the principle that the human body is not subject to commodification. Bodily material and the information derived therefrom would thus be controlled and protected by an expanded doctrine of informed consent of the person wherein control is founded on principles of inviolability and integrity of the person and penalties for any harm resulting from non compliance are instituted. As we have seen, such an approach would impose additional duties on physicians and geneticists to disclose not only attendant risks and benefits of medical procedures but also provide choices for all intended uses of a patient's bodily materials.

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129 A. Berger, ed., *Transactions of the American Philosophical Society: Encyclopedic Dictionary of Roman Law* 43:2 (Philadelphia: The American Philosophical Society, 1953) at 677 as cited in Marusyk & Swain, *supra*, note 1, at 381.

130 Marusyk & Swain, (1990), *supra*, note 124, at 15.

Under a personal rights approach the body is market inalienable; that is, organs or tissue can be transferred by gift but cannot be sold for valuable consideration.[131] However, once technology and labour intervene to alter what was once simply excised human material into a valuable market commodity, it then enters the market.[132] In this way, based again on the doctrine of informed consent, the individual from whom the material originates is respected, and the attending physicians, researchers and institutions, and society at large, can all benefit equally.

In light of the foregoing, the Commission recommends that legislation should be enacted directing the courts to take an expanded approach to the characterization of human genetic material as an extension of the person, and thus crucial to his or her bodily integrity, and requiring express informed consent for any present or future use. Such an approach may succeed in promoting a humane and non-reductionist view of the individual and will encourage the respect not only of genetic diversity but of the diversity of individual beliefs and religious convictions.

The Commission recommends, accordingly, that section 11 of the *Health Care Consent Act, 1996* should be amended to expand the notion of informed consent. This requires the creation of a legal obligation for institutions and physicians to inform patients of any disposal policies or of any uses that will be made of tissue/cells removed for *diagnostic* sampling, or for *therapeutic* purposes.

The Commission further recommends that informed consent with regard to *research* on excised tissue should be express and written, notwithstanding section 11(4) of the *Health Care Consent Act, 1996,* which provides that consent may be express or implied. However, anonymous epidemiological research should be exempt from this requirement.

In addition, the Commission recommends that diverse forms should be created by the appropriate regulatory bodies in order to obtain the signature of the research subject with regard to such research. Such forms should encompass a number of different actual and prospective options for the different types of research and banking of excised tissue/cells in order to best meet the personal present and future needs and wishes of the patient/participant in that regard. Any personal, professional, financial or other interest of the physician/researcher should be disclosed.

The Commission recommends that blood relatives should have access to stored DNA where necessary for their own medical diagnosis, and that the transfer of any tissue/cells in exchange for valuable consideration should be prohibited. Finally, the Commission recommends that, regardless of the approach ultimately adopted, a regulatory body should be established in order to monitor and control the establishment and activities of any private or

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131 See Horton, *supra*, note 39, at 218. Note that a property interest does not necessitate having the full gamut of ownership rights. The right to control the way in which one uses his body and body parts is sufficient to find a property interest.

132 See the third tier of Marusyk & Swain's proposal, *supra*, note 130, and accompanying text.

public DNA banking facility. Such a body would certify such establishments, and would create and enforce minimal standards for quality assurance in terms of services and personnel.

CHAPTER 5

DNA PATERNITY TESTING

1. INTRODUCTION

DNA profiling determines, to a high degree of certainty, a person's identity or familial relationship with others, and must be distinguished, therefore, from other forms of genetic testing, which are diagnostic tools used to identify hereditary health conditions and illnesses.[1] The technique, originally called "fingerprinting" due to the uniqueness of each individual's[2] profile as well as to its much publicized applications in criminal law and forensics, is now known as DNA profiling. The utility of DNA testing in resolving other enigmas of identity may not have captured the public's attention to the same degree as certain murder trials have, but the application of this technology in civil proceedings raises just as many complex legal and ethical questions.

In affiliation matters, conventional blood testing[3] has long been practiced but genetic profiling has vastly improved the quality and certainty of conclusions that can now be reached. Whereas blood group testing could only exclude a person, usually an alleged father, in the determination of a child's parentage, DNA profiling, which can be performed on organic substances other than blood,[4] can prove, almost irrefutably, close consanguine relationships such as paternity, maternity, and fraternity.[5] For better or for worse, this new technology thrusts biological truth into the limelight.

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1 See *supra*, ch. 2.

2 With the notable exception of identical twins.

3 Red blood cell antigens identification tests classified according to the ABO, Rh, Kell, Kidd, Duffy or MNS systems; the HLA system which examines white blood cells as well as testing of red blood cell enzymes and of serum proteins. When used in combination, these tests either *exclude* an alleged father from paternity or indicate, with varying probability, that he *could be* the biological father. See L.W. Morgan, "Attacking Blood Tests in Paternity Cases" (1992) 4:5 Divorce Litigation 89 at 91.

4 For instance, semen, bone marrow, saliva, urine, hair roots and tissues like skin. U.S. Congress, Office of Technology Assessment, *Genetic Witness: Forensic Uses of DNA Tests*, OTA-BA-438 (Washington, DC: U.S. government Printing Office, July 1990) at 15.

5 M.-C. King, "Invited Editorial: Genetic Testing of Identity and Relationship" (1989), Am. J. Hum. Genet., 179; L.A. Tonelli, K. Markowicz et al., "Use of Deoxyribonucleic Acid (DNA) Fingerprints for Identity Determination: Comparison with Traditional Paternity Testing Methods" (1990), 35:6 J. Forensic Sciences 1265; R. C. de Linval, " C'est toi mon papa?" (11 Nov. 1993), Journal du Barreau at 3.

In Canada, the technique has proved the paternity of a man who had undergone a vasectomy and who, against all odds, impregnated his wife.[6] It has also established the identical twinship of sisters before a transplant operation in order to diminish the risk of rejection.[7] Use of the procedure has also been made with the identification of infants who have been abandoned, kidnapped, or switched at birth.[8] In Argentina, it has facilitated the return of children, born in prison to political dissidents who were later assassinated, to their biological relatives.[9]

Testing may also be performed in post-mortem paternity suits or when a will is contested by potential heirs.[10] To ensure transmission to one's "true heirs", a blood sample can be stored and the testator can stipulate that claimants to his or her estate will have to undergo testing in order to establish a "match".[11] Furthermore, in immigration proceedings, where laws provide that applicants for entry must be related to their sponsor, DNA profiling is currently being used in several countries to demonstrate kinship. Recourse to such testing has exposed fraudulent claims and facilitated the family reunification process for those arriving from countries where official identity records are scarce or easily falsified.[12] The identification of unrecognizable human remains with DNA fingerprinting can also provide bereaved families with a certain degree of relief and closure by allowing them to give their loved ones proper burials.[13] Similar concerns have prompted the United States army to establish a data bank containing the genetic records of soldiers sent to war.[14]

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6 "DNA Testing Provides Sperm Evidence" (July 1993) *Globe and Mail*..

7 C. Mullen, "DNA Tests Proved Twin Sisters Are Identical" (Aug. 1992) *Edmonton Journal,* at 11.

8 E.R.B. McCabe, "Applicàtions of DNA Fingerprinting in Pediatric Practice" (1992), 120 J. Pediatrics, 499 at 506.

9 *Ibid.*, at 507. The analysis of mitochondrial DNA that is transmitted by the mother made the reunions possible.

10 In Belgium, post-mortem testing was ordered by a court in order to establish paternity. The judge ruled that the right of the child to know the identity of his father was of greater importance than the integrity of and respect due to the corpse: "Comment se réserver la preuve d'une filiation paternelle après le décès du géniteur présumé" (1989), 120 Journal des procès, 32 at 35. In the Canadian case of *Lee* v. *Horne* [1993] B.C.J. no 1894 (QL), a man left the bulk of his estate to the children of his deceased daughter. The man's ex-wife had also given birth to four sons; while all bore his surname, only the first two had been born during the marriage, the second one between the issuance of the divorce petition and the granting of the decree. All believed the deceased to be their father although they did not know him well. During the contestation of the will, genetic profiling was performed on a blood sample remaining from the testator's last hospitalization and on samples drawn from all four men. No matches were found and, accordingly the action was dismissed.

11 This is a service offered by the Helix Biotech Corporation in Canada.

12 A. Grubb & D.S. Pearl, *Blood testing, AIDS and DNA Profiling: Law and Policy,* (Bristol: Family Law, 1990) at 159-172; J. Clay "Genetic Evidence in Canadian Courtrooms: A Summary of DNA Technology and its Legal Applications" (1993) The Barrister 5.

13 McCabe, *supra*, note 8, at 507, refers to DNA testing of a skull that was identified as being from a girl who had disappeared in the desert several years earlier. See also J.-Y. Nau, "Les victimes de la catastrophe du

As a more refined and precise method of clarifying familial relationships, DNA testing is becoming more prevalent in civil proceedings pertaining to child support as well as to custody and access. While most actions relate to questions of paternity, maternal relationships may sometimes be challenged, particularly in cases where new reproductive technologies have been utilized. The California case of *Anna J.* v. *Mark C.* found that the gestational mother of a child carried subsequent to an embryonic transfer could not be declared by the court to be the "natural" mother, nor was there any basis for granting visitation rights, as she was not in any way genetically related to the infant.[15]

As genetic profiling becomes an accepted means of proving genetic kinship, and hence a crucial factor in the courts determination of parental duties and obligations, and children's rights, such testing, more than any other truth-finding method, will crystallize the debate between the conflicting values of biological and emotional truth as well as those between family stability and the child's best interests. Awareness of the difficulties raised by these conflicting values are evidenced by the manner in which other jurisdictions have addressed the advent of this new type of evidence.

In Denmark, all profiling must be ordered by the courts. The judge determines what type of evidence is necessary to prove paternity and can order that DNA analysis be performed on parties to the filiation action.[16] The Swedish government's attempt to locate and collect maintenance from the fathers of 14,000 children sired during Mediterranean holidays resulted in officials tracking down the foreigners named by the mothers and giving them the choice of signing an acknowledgment of paternity or giving a blood sample for DNA testing.[17]

In Britain, section 20 of the *Family Law Reform Act 1969* provides for blood testing at the discretion of the court and upon request of parties to the proceedings. While an updated provision (section 23 of the *Family Law Reform Act 1987*) mentioning "scientific tests" and "bodily samples" has been adopted by parliament to recognize the increasing use of DNA technology in paternity matters, it has yet to come into force. It has been argued that DNA testing is covered by the original law since it can be performed on blood. However, this new

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mont Saint-Odile ont été identifiées grâce aux empreintes génétiques", *Le Monde*, 31 March 1992, where the identification of the dismembered victims of an airplane crash is discussed.

14 "DNA Dog Tag or Genetic ID?" (June 22, 1992) *Time* at 16-17; W. Melillo, "Genetic Record Will Help Identify Unknown Soldiers" (January 14, 1992) *The Washington Post* .

15 G.J. Annas, "Using Genes to Define Motherhood - The California Solution" (1992), 326:6 New Engl. J. Med. 417.

16 L. Nielsen & S. Nespor, *Genetic Test, Screening and Use of Genetic Data by Public Authorities in Criminal Justice, Social Security and Alien and Foreigners Acts* (Copenhagen: Danish Centre for Human Rights, 1994) at 21.

17 G. Charles, "Génétique: Tous en fiches" (20 mars 1992) *L'Express* 46 at 50; of 942 Spaniards named by the mothers, 383 refused to sign acknowledgments and were summoned to the Swedish embassy in Madrid to have blood samples drawn; of 550 Italians, 172 refused to sign the paternity declarations and not one of the 60 French men denied paternity.

provision improves existing law significantly by allowing the court to order the tests on its own motion. It also recognizes, by the use of the term "parentage", that DNA can establish maternity as well as paternity. It has been recommended, on this basis, that the section be implemented in the near future.[18] A judicial ruling has also determined that paternity cases involving previously inconclusive blood tests can be reopened to take advantage of the new genetic profiling technology.[19] Furthermore, since the creation of the Child Support Agency in 1992, single mothers are obliged to reveal the names of their children's fathers in order to receive social assistance. All these factors have contributed to a great increase in DNA paternity testing in the context of support hearings.[20]

In 1989, the "Comité consultatif national d'éthique" in France, proposed that, in civil and family law proceedings, where biological proof may not always be necessary to establish a child's parentage,[21] the judge should have total discretion and control in ordering DNA tests and should carefully consider the child's interest and the stability of families before doing so.[22] In 1994, French law was amended in order to give effect to these recommendations. Hereinafter, identity testing will be performed in the context of filiation or child support proceedings only upon judicial order and with a person's consent.[23]

In the United States, a patchwork of statutes provides for the admissibility of conventional blood test results in paternity proceedings.[24] The laws tend to differ substantially, however, on standards of proof, admissibility of evidence, standing, and

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18 Grubb & Pearl, *supra*, note 12, at 173-175.

19 *H.* v. *O.*, *The Times*, July 8, 1991.

20 R. Collins & A. MacLèod, "Denials of Paternity: The Impact of DNA Tests on Court Proceedings" (1991) J. Soc. Wel. & Fam. L. 209.

21 Civil law jurisdictions have specific rules whereby filiation cannot be contested if the individual's act of birth and possession of status (a notion that emphasizes the social, as opposed to biological, reality of parent-child relationships) are consistent. See s. 322, 322-1 and 334-9 of the *Civil Code* of France and in Quebec, art. 530 C.C.Q.

22 Comité consultatif national d'éthique pour les sciences de la vie et de la santé, "Avis relatif a la diffusion des techniques d'identification par l'analyse de l'ADN (1989)" in *Les avis de 1983 à 1993* (Paris: 1993) at 258.

23 Art. 16-11 Code Civil, Loi no. 94-653 du 29 juillet 1994 relative au respect du corps humain. (Translation: Law No. 94-653 of 29 July 1994 on respect for the human body, (1994) 45 (4) Int. Digest Health Legis. 498. The Code de santé publique also permits genetic profiling for medical or research purposes in state approved facilities and projects. Penal sanctions are provided for in cases where the law is contravened. See art. L.145-15 to L.145-21, Code de Santé publique Loi no. 94-654 du 29 juillet 1994 relative au don et à l'utilisation des éléments et produits du corps humain, à l'assistance médicale à la procréation et au diagnostic prénatal. (Translation): Public Health Law No. 94-654 of 29 July on the donation and use of elements and products of the human body, medically assisted procreation, and prenatal diagnosis (1994) 45(4) Int.. Digest Health Legis. 473 at 482.

24 The *Uniform Parentage Act,* 9B U.L.A. 295 (1987), enacted in 18 states; The *Uniform Act on Paternity*, 9B U.L.A 350 (1987) enacted in six states; *Uniform Act on Blood Tests to Determine Paternity* is still in force in seven states although it has been superseded by ss. 7-10 of the previous statute; finally, other states have their own specific statutes governing paternity blood testing See Morgan, *supra*, note 3, at 89.

jurisdiction in filiation proceedings and attempts to achieve legislative uniformity throughout the nation have thus far been unsuccessful.[25] While DNA tests have sometimes been ordered by the courts upon request of the parties or on the basis that they can be performed on blood samples,[26] only a few states have statutes that specifically include DNA testing in provisions regarding the determination of paternity.[27]

Conventional blood testing and DNA profiling in the context of family law proceedings in Ontario and in other Canadian jurisdictions need to be examined. The legal issues regarding identity testing can be subdivided into three areas: (1) questions of the admissibility of DNA evidence, applicable statutory and jurisprudential norms regarding presumptions of paternity and court-ordered testing; (2) issues surrounding personal liberty, consent, and physical integrity under the *Canadian Charter of Rights and Freedoms* [28] in light of adverse inferences that can be drawn by courts upon an individual's refusal to consent to testing; and (3) the practical, social, and legal interests of the state, women, and children in using tests with such a high degree of certainty. These legal issues, discussed below, will provide a context for relevant policy recommendations.

2. GENETICS AND FAMILY LAW IN ONTARIO

With the breakdown of the traditional two-parent nuclear family, reform in Ontario law in the past two decades has addressed the explosion and needs of alternate familial units, such as those headed by single mothers, either unwed or divorced. The advent of new reproductive technologies, such as egg or sperm donation, surrogate motherhood, and embryo transfer, has also had an impact on how society defines and treats families.[29] With the proliferation of a whole new range and number of familial structures, relationships, and roles,[30] many of them temporary, paternity testing is a tool that can provide indications of genetic links as well as clarify or complicate legal ties between individuals. Due to its accuracy, DNA testing may further revolutionize the field of family law and, as such, the reliability and admissibility of such evidence before the courts needs to be examined. Consideration must also be given to

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25 E.D. Shapiro, S. Reifler & C.L. Psome, "The DNA Paternity Test: Legislating the Future Paternity Action" (1992-93) 7 *Journal of Health and Law* 1.

26 B.M. Knoppers, M.-A. Grimaud, C. Choquette & S. Le Bris, "Les tests génétiques à des fins d'identification", (1994) (in press) at note 124.

27 D.O. Andrews, "DNA and Dads: Considerations for Louisiana in Using DNA Blood Tests to Determine Paternity" (1992) 38 *Loyola Law Review* 425 at 446, note 128 and B.M. Knoppers et al., *ibid*, note 123.

28 Part 1 of the *Constitution Act*, 1982, being schedule B of the *Canada Act*, 1982 (U.K.), c. 11 (hereinafter the *Charter*).

29 E. Sloss and R. Mykitiuk, "The Challenge of the New Reproductive Technologies to Family Law" in *Legal and Ethical Issues in New Reproductive Technologies: Pregnancy and Parenthood* (Research Studies of the Royal Commission on New Reproductive Technologies, vol. 4) (Ottawa: Minister of Supplies and Services Canada, 1993) 339.

30 See for instance M. Eichler and M. McCall, "Clarifying the Legal Dimensions of Fatherhood" (1993) 11 Can. J. Fam. L. 197.

this technology's impact upon statutory provisions regarding blood tests, presumptions of paternity, and their rebuttability.

Scientific evidence, by its very nature, can often impress and convince the layman without being based upon a solid and proven scientific foundation. While the contributions and relevance of DNA technology, in determining questions of identity, are not disputed in either the scientific or the legal milieu, the probative value of particular DNA test results entered into evidence is always contestable. Scientific reports are usually carefully evaluated in terms of the methodology used by the laboratory performing the tests as well as the expertise of the person who interprets the results.[31] The possibility of human or technical error remains. Likewise, variations in procedural methods and security measures in different testing facilities can result in parallel variability. At present, DNA testing facilities are unregulated and neither procedural norms nor professional standards for their personnel have been established.

Despite the novelty of DNA profiling technology, the scientific validity and accuracy of the method has been called into question only once in Canadian filiation proceedings. In the case of *Kotyk* v. *Jackson*,[32] the respondent contested the inclusion of genetic evidence on the basis that it was too general. The testing report concluded that he was the father of the child without disclosing the degree of probability or the number of probes used to perform the test. The court ruled that the medical report was ambiguous and inadequate to prove, on a balance of the evidence, that he was in fact the child's father.

Currently, paternity testing finds its most useful applications in matters of child support, custody, and access. In both areas, the determination of who is a "parent" is crucial since section 31(1) of the *Family Law Act* [33] states that "every parent has an obligation to provide support, in accordance with need, for his or her unmarried child who is a minor". Section 20(1) of the *Children's Law Reform Act* [34] provides that the mother and father of a child are equally entitled to custody. Paternity testing, whether by conventional methods or by DNA analysis, is thus a useful evidentiary tool in proving the existence of a biological relationship establishing legal rights to, and corollary obligations of, financial support, access, and visitation.

As with other provincial jurisdictions, Ontario has enacted specific rules of filiation as well as legal procedures in order to determine, contest, or confirm a child's parentage. Section 4(1) of the *Children's Law Reform Act* provides as follows:

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31 Morgan, *supra,* note 3, at 92-95.

32 (1991) 96 Sask. R. (2d) 175

33 R.S.O. 1990, c. F.3.

34 R.S.O. 1990, c. C.12.

> 4.—(1) Any person having an interest may apply to the court for a declaration that a male person is recognized in law to be the father of a child or that a female person is the mother of a child.

Such a declaration is made "for all purposes", under section 4(4), by the superior courts. Whereas maternity, under section 4(3), is established simply by a balance of probabilities, the rules to establish paternity are more complex because of the historic legal distinctions, now abolished in Ontario,[35] between legitimate and illegitimate offspring. Presumptions of paternity thus apply regardless of the biological paternity, which is said to be misattributed as much as twenty percent of the time.[36] Section 4(2) establishes that declarations of paternity made by the courts will follow the presumptions, unless *non-paternity* is established by a balance of probabilities. In Ontario, these presumptions are set out in section 8(1), which provides:

> 8.—(1) Unless the contrary is proven on a balance of probabilities, there is a presumption that a male person is, and he shall be known in law to be, the father of a child in any one of the following circumstances:
>
> 1. The person is married to the mother of the child at the time of the birth of the child.
> 2. The person was married to the mother of the child by a marriage which was terminated by death or judgment of nullity within 300 days before the birth of the child or by divorce where the decree *nisi* was granted within 300 days before the birth of the child.
> 3. The person marries the mother of the child after the birth of the child and acknowledges that he is the natural father.
> 4. The person was cohabiting with the mother of the child in a relationship of some permanence at the time of the birth of the child or the child is born within 300 days after they ceased to cohabit.
> 5. The person has certified the child's birth, as the child's father, under the vital statistics act or a similar Act in another jurisdiction in Canada
> 6. The person has been found or recognized in his lifetime by a court of competent jurisdiction in Canada to be the father of the child.

In cases of conflict in which the application of these presumptions point to two different men, section 8(3) provides that no presumption of paternity shall be made and no person will be recognized in law to be the child's father. Such a situation illustrates one instance in which a declaration of paternity might be necessary to ensure maintenance for a child or visitation rights. It is also interesting to note that under section 6 of the *Children's Law Reform Act,* the courts have the discretionary power to revise declaratory rulings of parentage if new evidence comes to light or becomes available. DNA testing could thus potentially provide men who

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35 *Ibid.*, s. 1(4).

36 C.T. Caskey & H.A. Hammond, "DNA Fingerprinting in Utero - Draft of a Case Study" [unpublished] address to the Genetics, Religion and Ethics Conference, March 13-15, 1992.

feel they were wrongly declared fathers by the courts with the opportunity to reopen their cases and have their obligations ended.

In any civil proceeding in which a child's parentage has been called into question, provincial law provides for blood testing upon judicial leave. Thus, lower courts, which cannot make declarations of paternity "for all purposes", can nonetheless make findings or determinations of paternity for limited purposes in proceedings in which they might be necessary to resolve the dispute.[37] While provisions on blood testing are found in the *Children's Law Reform Act,* which deals primarily with custody and access, the court in *Re H. and H.* held that the relevant sections are "available to provide a court with the advantage of blood testing in civil matters where the question on parentage arises as a material, but ancillary matter, and is not limited solely to circumstances where a declaration of parentage is sought under ss. 4 or 5 of the Act".[38]

Testing cannot be ordered by the court upon its own motion and results of paternity tests performed without the court's permission will not be permitted to be entered into evidence.[39] Section 10 the Act thus states:

> 10.—(1) Upon the application of a party in a civil proceeding in which the court is called upon to determine the parentage of a child, the court may give the party leave to obtain blood tests of such persons as are named in the order granting leave and to submit the results in evidence.
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> (2) Leave under subsection (1) may be given subject to such terms and conditions as the court thinks proper.

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37 M. Wilson, "Impacts of Paternity Uncertainty in Family Law" (1987) 45:2 *U. of T. Faculty of Law Review* 216 at 232.

38 (1979) 25 O.R. (2d) 219 at 221.

39 *Silverberg* v. *Silverberg,* [1990] O.J. No. 294 at 8. This does not mean, however, that private parties cannot make use of DNA testing technology and facilities outside of court proceedings. DNA profiling can be performed on a private basis, for personal purposes, be they peace of mind, blackmail or revenge. For instance, a British man who, persuaded that another man had fathered his son, had a blood sample stored before his death and made provisions in his will that the boy's be tested in order to confirm or exclude a genetic match. The will provided that the wife be disinherited if the test demonstrated her infidelity, but in fact, the child turned out to be her husband's; G. Charles, *supra* , note 17, at 48.

While the words "blood tests" are not explicitly defined,[40] DNA testing has been permitted under this definition,[41] either as a primary test or as a follow-up measure where traditional blood testing methods have not provided conclusive results.[42] Because of its ability to determine biological paternity with some degree of certainty, this new technology will no doubt become the evidentiary standard. Testimonial evidence, often contradictory, as to sexual contact between the parties, may, as a result, have less probative value. Furthermore, when faced with the prospect of a DNA test, biological fathers attempting to evade their responsibilities, may not wish to spend expensive court time contesting paternity and may be more willing to come to a settlement regarding child support.

In Ontario, the courts have ruled that the presumption of paternity need not be successfully rebutted in order to request leave for blood testing. In the case of *D.H.* v. *D.W.*,[43] where the alleged lover of a married woman sought to establish his paternity with regard to one of her children, the court wrote:

> While there must first be an issue as to parentage in a civil proceeding before leave to obtain blood tests can be granted, I am unable to agree with my brother judge in the case of F.G. that there can be no issue before the court unless the applicant can first prove on a balance of probabilities that someone other than the presumed father is the father of the child. In many instances - such as this case - this would have the practical effect of requiring the applicant to meet the ultimate burden on the issue of parentage before leave to obtain evidence in support of his case could be obtained.

However, a rebuttal of the presumption may still be necessary in cases in which a man wishes to deny his paternity with regard to a child theretofore considered his own.[44] It is noteworthy that in child support proceedings, the *Family Law Act*[45] defines, at section 1(1), "parent" as biological progenitor or adoptive parent of a child as well as a person who has

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40 Section 11 of the *Children's Law Reform Act* provides that the government may make regulations governing court authorized blood tests but, as of yet, no such regulations have been enacted. British Columbia is the only Canadian jurisdiction that has enacted specific provisions regarding genetic profiling in family law matters: Rule 10 of the *B.C. Provincial Court (Family) Rules* (1993) gives the following definition: "In this rule paternity tests include human leukocyte antigen tissue tests and tests of the deoxyribonucleic acid (DNA) in tissue or blood to identify the inheritable characteristics of the tissue or blood". In New Brunswick, the *Child and Family Services and Family Relations Act*, R.S.N.B. 1980 c. C-2.1, permits at s. 110(1) " blood tests and such other tests as the court considers appropriate"; s. 8 of the Newfoundland's *Children's Law Act,* R.S.N. 1990, c. C-13, refers to "blood or other genetic tests."

41 See the cases of. *S.* (C.) v. *L..(V.)* [1992] 39 R.F.L. (3D) 294 (Ont. Ct. of Justice); *S.M.* v. *J.S.*, [1993] O.J. no. 2959 (QL); and *Russell* v. *Russell* (1994) Unreported, June 24, 1994 (Alta. Q.B.).

42 *S.* (C.) v. *L..(V.)*, *ibid.; Parkin* v. *MacMillan*, [1990] B.C.J. No. 2312 (QL); In *D.P.D.* v. *J.A.K.*, [1990] B.C.J. No. 2369 (QL), the judge refused to order DNA testing despite inconclusive serological test results because other types of evidence permitted resolution of the case.

43 [1992] O.J. No. 1737 (QL).

44 See *F.G.* v. *F.G* , (1991) 32 R.F.L. (3d) 252.

45 *Supra*, note 33.

demonstrated a settled intention to treat the child as a one of his or her family. Accordingly, fathers who raise the issue of the biological origins of their children in maintenance proceedings may be refused leave for blood testing, on the basis that the matter of biological paternity is irrelevant.[46] More importantly, regardless of the quality and quantity of proof advanced in obviating a paternity claim, granting leave for appropriate blood testing is a discretionary matter to be decided by the court (section 10(2)).

A number of factors are considered in this exercise of the courts discretion and apply regardless of the testing method used. The *bona fides* of the applicant must be closely examined and "where there is reason to believe that the application is brought for some ulterior improper motive, the court may well be justified in denying leave".[47] Testing will not be permitted simply on the basis of suspicion or rumour,[48] or so that the petitioner can embark on a "fishing expedition".[49] In certain cases, the length of time that has elapsed before filing an action may be examined[50] although the child who is in need of financial assistance should not usually be penalized for a parent's tardiness. Further, while the child's best interests[51] in allowing genetic testing are considered, they are often outweighed by the interests of justice in uncovering the biological truth of parentage.[52] The courts have thus been led to rule that refusal to grant leave for blood tests will be the exception, rather than the rule.[53] However, the implications of DNA test results and their consequences upon the lives

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46 *D.A.D.* v. *M.D.*, [1992] O.J. No. 1984 (QL); *Zbirun* v. *Zbirun*, [1991] S.J. No. 587 (QL).

47 *D.H.* v. *D.W.*, supra, note 43; see also *B.E.P.* v. *S.D.P.*, [1993] O.J. No. 203 (QL); *R.B.* v *L.G.*, [1992] O.J. No 1654 (QL); *F.(M.)* v. *S.(R.)*, [1991] O.J. No. 2454 (QL); *McCartney* v. *Amell*, 35 O.R. (2d); *Re H. and H.*, *supra*, note 38; *Re Bagaric* v. *Juric et al.*, 29 O.R.(2d) 481 and *Mohammed* v. *Ali*, [1987] O.J. No. 1817 (QL).

48 See, for instance, *B.E.P.* v. *S.D.P.*, supra, note 47; *R.J.* v. *S.M.*, [1990] B.C.J. No. 348 (QL).

49 *Ibid.*; K.(S) v. G. (T.) [1991] O.J. No 2444 (QL); *M.C.* v. *L.A.C.*, [1990] B.C.J. No. 134 at 20 (QL); *D.R.* v. *P.M.*, [1992] B.C.J. No. 2340 (QL); *E. (M.A.)* v. *L.(C.)*, (1993) 82 B.C.L.R. (2d) at 21.

50 *Stephenson* v. *Willoughby*, [1987] O.J. No. 1801 (QL); *B.E.P.* v. *S.D.P.*, *supra*, note 47; *McCartney* v. *Amell*, *supra*, note 47.

51 See the discussion, *infra*, this ch., sec. 4. Also: *D.H.* v. *D.W.*, *supra*, note 43, *Re Wilson and Stewart*, (1982) 45 O.R. (2d) 95 ; *C.B.* v. *M.I.*, [1994] O.J. No. 294 (QL); *Palmateer* v. *Daley*, [1990] O.J. No. 2196 (QL); *D.A.D.* v. *M.D.*, *supra*, note 46. See K. Blomquist-Shinn, "Family Law: A New Requirement for Paternity Determinations in Kansas - Determining if Blood Tests are in the Best Interest of the Child" (1990) 30 *Washburn Law Journal* 113 at 118.

52 *Re H. and H.*, *supra*, note 38; *F.(M.)* v. *S.(R.)*, *supra*, note 47; *R.B.* v. *L.G.*, [1992] O.J. No. 1654 (QL); *D.R.* v. *P.M.*, [1992] B.C.J. No. 2340 (QL)

53 *F.(M.)* v. *S.(R.)*. *supra*, note 47. However, see *contra*, the recent decision of *L.(F.A.)* v. *B.(A.B.)* Man. C.A. June 12, 1995 as cited in (August 25, 1995) 15 (15) Lawyers Weekly where the court, per Twaddle J.A., refused to order blood tests of a child to determine paternity because it would prove disruptive to the family unit in which the child resided.

of families and children, may require more serious contemplation by the courts before leave is granted.[54]

3. CHARTER CONSIDERATIONS AND ADVERSE INFERENCES

Since 1982, Canadian courts have measured the interests of justice in paternity testing matters against the rights and civil liberties entrenched in the *Charter of Rights and Freedoms.*[55] Since DNA profiling and conventional blood testing may, by their very nature, violate certain rights that Canadian society has chosen to protect, the drawing of even a tiny amount of blood[56] raises fundamental questions of personal choice, liberty, privacy and bodily integrity under sections 7 and 8 of the *Charter*. Once leave for testing has been granted by the court, the consequences of a party's refusal to give blood need to be explored within the context of these rights. Section 10(3) of the *Children's Law Reform Act* [57] states:

> 10.—(3) Where leave is given under subsection (1) and a person named therein refuses to submit to the blood test, the court may draw such inferences as it thinks appropriate.

Regardless of the testing being performed or refused, the judge can draw his own conclusions as to paternity and make a ruling in light of other evidence. The putative father's or mother's refusal (for herself or for her child[58]) can be interpreted in any way deemed appropriate. The law thus permits the refusal by a party to cooperate in the determination of a child's parentage to be viewed as an indication that he or she has something to hide or may be

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54 See v *Saul. Himel* (1994) O.J. No. 2630 (Ont. Ct. of Justice) (Q.L.) where an ex-husband sought damages for (*inter-alia*) child support expenses against his ex-wife arguing that she had a duty to disclose her extramarital affair and the fact that one of the children of the marriage was not his biological child, the court held:

> For what appears to be purely monetary reasons, as opposed to moral reasons, S. has brought on this law suit against his former wife. K. was asked to take the paternity test, thereby dividing the children as a family unit, perhaps creating embarrassment for any or all of them. S. seeks to not only repudiate his on-going support for K but asks for damages against his former wife for the support which was paid and was used, not for her benefit, but for the benefit of K. This, in my view, offends public policy.

55 *Supra*, note 28.

56 According to the promotional materials of Helix Biotech Laboratories, between 1 to 5 ml. of blood are required. While DNA profiling can be performed on substances other than blood, such as hair, nail clippings and saliva, the sampling of which might be viewed as less physically invasive, blood remains the sample of choice as it contains the most DNA and, furthermore, s. 10 of the *Children's Law Reform Act*, provides only for blood testing.

57 *Supra*, note 34.

58 Section 10(4)(a) of the *Children's Law Reform Act* provides that where a person is a minor, consent for blood testing shall be given by the person having care and control of the minor. In most cases this person is the mother.

attempting to evade important responsibilities. In the British case of *Re Evans and Martin* v. *Hammond*, it was stated as follows: [59]

> In a civil case, the refusal of one party to produce materially relevant evidence in their possession would, absent a reasonable explanation, almost inevitably result in the trier of fact concluding that such evidence would be either (a) helpful for the opposite party and/or (b) harmful to the one who refused to produce it .

Negative inferences will likely be drawn by the courts when faced with an unjustified refusal or one that cannot be reasonably explained.[60] However, courts have been unwilling to draw adverse inferences where a refusal was given by a comatose man's legal representative[61] and are likely to be similarly unwilling where a refusal is based upon religious convictions or serious health concerns. An irrational fear of contracting AIDS will, however, be rejected as a justified refusal and testing will be allowed.[62]

It has been argued that statutory provisions regarding adverse inferences are contrary to section 7 of the *Charter* because they force individuals to submit to a medical procedure against their will. The ruling in *Re Stewart and Wilson* [63] determined that leave for testing, as granted by the court, is not the type of order that, if refused, might result in a citation for contempt of court and possible incarceration. In *Re N and D.,* it was found that section 10 of the *Children's Law Reform Act* did not violate section 7's protection of "life, liberty and security of the person" because it does not authorize the forcible taking of blood and as such does not interfere with the physical integrity of the individual. The judge ruled that a request for blood testing is nothing more than "an ordinary procedural step" in an action.[64]

In 1988, Rutherford J. of the Ontario Supreme Court wrote: [65]

> The impugned provision requires that the party seeking a blood test must apply to court for leave to obtain the tests and to then submit the results in evidence. If the court grants leave to obtain blood tests, the individual is nonetheless entitled to refuse to submit to the tests pursuant to s. 10(3) of the Act. The result of such a refusal is to provide the court with the power to "draw such inferences as it thinks appropriate".

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59 (1979) 1 F.L.R.R. 113.

60 *P.(L.)* v. *J.(W.)*, [1989] N.B.J. No. 619; *L.G.S.* v. *G.H.*, [1993] B.C.J. No.1595. See also L.(F.A.) v. B. (A.B.), (1995) 6 W.W.R. 570 (Man. C.A.) where the respondent called no evidence, the court's inference that the respondent either did not want to know who was the father or did not think the time was right to determine the issue negated negative inferences that might otherwise be drawn from the respondent's refusal to testify or to submit to blood tests.

61 *Francis* v. *Robertson*, [1987] O.J. No. 1513

62 *Vincelli* v. *Lorenzetto*, [1993] B.C.J. No. 2011.

63 *Supra*, note 51.

64 (1985) 49 O.R. (2d) 490 at 496

65 *K.P.* v. *P.N.* , (1988) 15 R.F.L (3d) 110 at 111-12 (Ont. S.C.)

> The drawing of an inference against a party who does not provide relevant evidence in a court proceeding, when that evidence is within the exclusive control of that party, does not constitute compulsion or coercion. It is an evidentiary matter to be considered in the context of a civil proceeding in which paternity is an issue.

As genetic testing provides a conclusive determination of paternity, refusal to be tested may be judged even more harshly than it has in the past and could result in the quasi-automatic drawing of adverse inferences against the refusing party.

Some putative fathers have argued that legislation authorizing the courts to grant application for leave to obtain blood tests in paternity suits constitutes an unreasonable search and seizure under section 8 of the *Charter.* The Supreme Court of Canada has stated that the purpose of this provision is to prevent unjustified searches before they happen[66] and that evidence from blood samples taken without an individual's consent constitutes a violation of section 8 because it could bring the administration of justice into disrepute.[67] Regarding its application to section 10 of the *Children's Law Reform Act* , the judge in *Re N and D* weighed the state's interest in invading personal privacy against the individual's interest in being left alone: [68]

> Contrasting the positive or beneficial results of an order granting leave to obtain blood tests against the financial burden a respondent might face, yet recognizing the aforementioned lack of compulsion, I conclude that an order made under s. 10 would not constitute or cause an unreasonable search or seizure. For s. 8 to be violated, the search or seizure must be unreasonable. In a s. 10 situation, the taking of blood would not constitute an unreasonable search or seizure.

In *Crow* v. *McMynn*, it was also noted that "the minimal imposition upon the body and time of the putative father and the fact that a blood test could lead to a decision that would benefit a child, [blood testing] would not appear, on balance to be unreasonable".[69] Rulings in British Columbia have established that, unless a child is a party to an action, an order to submit to DNA testing in paternity proceedings will violate his or her section 7 and 8 rights.[70] In Ontario, section 10(4)(a) of the *Children's Law Reform Act* provides that the person having the care and control of the minor consents for the child, but in the case of *D.H.* v. *D.W.*, a guardian was appointed to provide consent and to represent the child's interests in the matter as neither his mother nor the mother's husband wished paternity testing to take place.[71]

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66 *Hunter* v. *Southam Inc.* , [1984] 2 S.C.R. 155.

67 In the impaired driving case of *R.* v. *Pohoretsky,* [1987] 1 S.C.R. 945

68 *Supra*, note 64, at 501. Likewise, in *Silber* v. *Fenske*, (1995) 11 R.F.L. (4th) 145 (Ontario Court of Justice) the court held that the taking of a blood sample to determine paternity was not unreasonable since the father could not be forced to give blood without his consent. The judge did note that according to s. 10 he could draw unfavorable conclusions based upon the refusal.

69 (1989) 49 C.R.R. 290 at 303.

70 *Carnaby* v. *Millar,* [1993] B.C.J. No.311 (QL); *Hardie* v. *Hardie,* [1993] B.C.J. No. 1249 (QL)

71 *Supra,* note 43.

Identity testing performed at the request of adult parties in a suit can create emotional upheaval in the lives of children and their families. The advantages of genetic certainty in matters of access and maintenance as well as with regard to the economic interest of the state thus need to be carefully weighed against the very real possibility of intruding upon a woman's privacy, to say nothing of upsetting a child's stability and security.

4. IMPLICATIONS OF DNA TESTING FOR THE STATE, WOMEN, AND CHILDREN

Concerning the economic arguments in favour of DNA testing, the judge in the case of *Re N. and D.*, wrote: "I am satisfied that the government, as well as the mother and child, have strong interests in a finding of parentage being made, in order that a support order might be made".[72] The question that has yet to be answered is whether these interests are the same. The government's interest is in getting mothers off the welfare rolls; the mother's interest is in providing adequately for her family's material needs; and the child's interest, (who undoubtedly gains from an improved living standard), is in having an untroubled, secure and stable familial environment. How, therefore, does one reconcile these divergent goals?

Generally speaking, single parent households have low incomes and many mothers depend on social assistance to make ends meet. Strains put on government budgets encourage policy makers to look for ways to make so-called "deadbeat dads" take financial responsibility for their offspring, regardless of their personal involvement in their lives. Where not so long ago judges were reluctant to make a man pay eighteen years of support for a child born of a short-lived tryst,[73] they now, with the help of paternity testing, make, and attempt to enforce, maintenance orders regardless of the circumstances of conception.[74]

DNA testing, by clearly identifying the biological father, permits the "right" person to pay and, as such, exonerates falsely accused putative fathers. Moreover, it has the potential to liberate taxpayers from additional fiscal burdens. Not only does the state have a strong incentive to push women to obtain child support from fathers, now it also has the technological means to ensure that parental obligations are properly attributed. Canadian welfare mothers may see themselves being refused assistance unless they reveal the identity of their child's father and petition them for support. It remains to be determined if forcing women to reveal such personal and intimate information will be deemed a serious violation of their rights to privacy.

In Alberta, government officials are often co-petitioners with the mother in paternity proceedings.[75] The Ontario case of *Rhan and Pinsonneault* mentions that the action was

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72 *Supra,* note 64, at 496.

73 *Re Rhan and Pinsonneault* (1980), 27 O.R. (2d) 210.

74 See Fisher, J's comments on the subject in *Mohammed* v. *Ali, supra*, note 47.

75 See Alberta (Director of Maintenance and Recovery) v. P. (T.), (1991) 37 R.F.L (3d) 275; D.S. v. Alberta (Director of Parentage and Recovery), [1993] A.J. No. 426 (QL).

undertaken at the instance of the welfare authorities.[76] British authors Collins and MacLeod state that the vast majority of women making use of DNA testing in their country are poor and single.[77] However, despite the fact that fewer fathers will be able to evade identification and maintenance orders, there is no guarantee that they will in fact pay child support and, in that sense, the state may not be much further ahead than it was before the advent of genetic paternity testing.

With regard to the mother's privacy interests, not so long ago, only a mother could know the identity of her child's father. With the advent of DNA profiling, the truth is now available to all parties. Whereas the technology may be useful to obtain a support order against a wayward father and has the potential to provide financial security for the child, it could also be a very destructive force in a woman's life, by exposing infidelity and damaging close personal relationships. Ostensibly, the test could even be used by a man to prove paternity in order to remove the children from the mother's custody. Despite the fact that a mother may wish to protect her children from the knowledge of their true heritage, the courts seem to believe that, in most cases, it is better for all involved that the truth be known. As the judge in *D.H.* v. *D.W.* wrote: "it is in the best interest of the child that, where a real issue as to parentage is raised, the truth be ascertained on the best evidence possible".[78]

While genetic profiling may find its most useful and straightforward application in assisting single mothers to obtain support from wayward fathers, matters may be considerably more complicated in other cases where, for instance, the children already know a certain person as their father and another man, a total stranger, claims paternity as a means to get access.[79] Testing can also be used as a weapon between warring ex-spouses who lose sight of the fact that, in the long run, only the children get hurt.

For instance, in the British Columbia case of *Goudie* v. *Goudie* ,[80] the biological parentage of two of a man's three children was questioned by his ex-wife. Reasonable access had been granted to the ex-husband but when the mother remarried (a man who was not the putative father but who was presented as a new father-figure), she wished to sever the ties between her former husband and the children she claimed were not his. When the original access orders had been made, the judge ordered DNA testing in order to resolve the paternity issue and wrote that:

> It is vigorously opposed because of the potential effect it may have on the children. It is vigorously supported on the ground that the ties of consanguinity could be relevant on the ultimate question of access.

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76 *Supra*, note 73.

77 *Supra*, note 20, at 211.

78 *Supra*, note 43.

79 *Ibid.*

80 *Goudie* v. *Goudie*, [1993] B.C.J. No. 1049 (QL).

> My view is that this evidence is potentially relevant and that the ultimate decisions on access should be made with the paternity results as an aspect of the overall picture to be placed before the court. Accordingly, I do order the testing as requested.

The test results established that Mr. Goudie was not the biological father of the two boys and the mother returned to court in order to terminate her ex-husband's visitation rights with them. The second judge noted that :

> The biological factor has been used to undermine and separate the younger children from Mr. Goudie, an unfortunate consequence of this is the creation of conflict, anger and confusion in the older child. There is no doubt that Mr. Goudie has genuine emotional bonds to all three of these children and that he views them all as his sons. Unfortunately, his anguish at the interference with and the restriction of his access has been yet another stress on these children. This combined with the petitioner's efforts to explain their paternity has sewn [sic] the seeds of confusion, altered the relationship between the children themselves and placed them in the middle of the conflict between the two people these children saw as their parents.

Mr. Goudie did, in the end, get limited access to the two younger children but by then much of the damage had been done.

This situation clearly illustrates what can happen when the courts place too much emphasis on fact-finding aspects of justice and not on enough on the interests of the children, who are most likely to be affected. Canadian law in this regard has been largely inspired by the much quoted words of Lord Denning: [81]

> [O]ver and above all the interests of the child, there is one overriding interest which must be considered. It is the interest of justice. Should it come to the crunch, then the interests of justice must take first place... In my opinion, a court...should have before it the best evidence which is available. It should decide on all the evidence, and not on half of it. There is at hand in these days expert scientific evidence - by means of a blood test - which can in most cases resolve the issue conclusively. In the absence of a strong reason to the contrary, a blood test should be made available. The interests of justice so require.

By reducing the impact of genetic profiling to a simple evidentiary matter, where the results of paternity tests are but one small piece of the evidence as they have been in the past, the courts may well be overlooking the fact that DNA technology will revolutionize family law. Rare are the instances in civil proceedings (requiring proof on the balance of the evidence) where the tribunal can be provided with evidence, which by its very nature, is beyond a reasonable doubt. DNA testing establishes paternity with ninety-nine percent accuracy and may therefore make it difficult for certain members of the judiciary to exclude,

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81 *S.* v. *S* ; *W.* v. *Official Solicitor,* [1970] 1 All E.R. 1162 (aff'd [1972] A.C. 24) at 1165; for cases where this passage has been followed or cited in Canada see *supra,* note 52. See also *S. (D.M.)* v. *C. (J.).* (1994) 120 D.L.R. 4th 581 at 585 where the court, in determining whether blood samples should be taken to establish paternity in an application against an estate, found that where blood analyses provide cogent and relevant evidence, all avenues of discovery should be available to the litigants in order to provide an answer to the question in dispute.

on the basis of equity, a father from his child's life.[82] Furthermore, regardless of whether test results are admitted into evidence or the outcome of proceedings, the actual impact of testing and the very real possibility that test results will be communicated to children must not be overlooked.

While family law provisions concerning maintenance, custody, and access all place a supreme emphasis on the child's best interest and do not necessarily favour biological links over emotional ties,[83] the unconsidered and hasty admission of DNA testing in affiliation proceedings, on the basis that it will provide the most precise indication of biological identity, may, nonetheless, lead the courts to favour a biological conception of parentage rather than one based upon who can provide the best care and upbringing for a particular child.[84] As the law stands today, the interests of justice will usually require that the best evidence be available to the tribunal, and under this guise, DNA testing will be ordered. The search for biological certainty may however, inevitably and regrettably, blur social, affective, and emotional truths and ties.

5. CONCLUSION AND RECOMMENDATIONS FOR REFORM

There are serious consequences linked to the introduction of DNA paternity testing in Canadian courtrooms as it will clearly distinguish social parents from biological parents at a time when the evolution of family law has moved away from an emphasis on genealogical origins towards respect of the real living context of the child and the family. In light of these difficulties, we have concluded that regulations should be passed by the Ontario government, pursuant to section 11 of the *Children's Law Reform Act,* that take into account the advent of DNA testing and its serious implications, for both family stability and for the well-being of the child. In particular, the Commission recommends that, pursuant to section 11(c) of the *Children's Law Reform Act,* DNA testing facilities should be monitored and accredited in order to ensure that laboratory standards and testing methodology for the purposes of section 10 of the Act are uniform and of high quality. The Commission further recommends that DNA identity testing should be permitted only with leave of a court of competent jurisdiction. With respect to the receipt of social assistance for economically disadvantaged mothers, the Commission has concluded, and therefore recommends, that such receipt should not be dependent upon the participation of women and children in DNA testing. Moreover, the Commission recommends that the courts should exercise caution in allowing leave for testing

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82 There have, however, been a few such verdicts in spite of conventional blood testing pointing to an extremely high probability of paternity. See, for instance, *Re Ledyit and Alford,* (1986) 58 O.J. No. 1226; *McIntosh* v. *Eccles,* [1987] O.J. No. 1804.

83 See for instance s. 24 of the *Children's Law Reform Act, supra,* note 34, as well as the definition of parent at s. 1 of the *Family Law Act, supra,* note 33.

84 See *Droit de la Famille 2219* J.E. 95-1295 (forthcoming in (1995) R.D.F.) where a father, not even 21 years old, proved his paternity through DNA testing and thereby prevented future adoptive parents from maintaining custody. However, see the recent cases of Z. (M.J.) v. Z.R. (A.M.) 1995 53 A.C.W.S. 95 (Ont. Ct. Gen. Div.) and L. v. L (1994) 114 D.L.R. 709 (Ont. Ct. Gen. Div.) where advances in genetics and reproductive technology illustrate a judicial sway in biological relatedness, (although paternity, it should be noted, was not at issue).

and that the interest of the child should be paramount in the decision. The interest of the child, with regard to genetic identity testing, should take into account the following factors: the child's past and present relationship with his or her parents; his or her physical, mental, and emotional needs; the stability of the child's current home environment (whether there is an ongoing family unit); and the child's knowledge of the paternity dispute. Finally, the Commission recommends that, in cases in which a declaration of paternity under section 4 of the *Children's Law Reform Act* has already been made, a time limitation should be enacted in order to limit the application of section 6, which permits the courts to reopen a case and revise their decision where new (in this case DNA) evidence is available and might result in a different verdict.

CHAPTER 6

INSURANCE TESTING

1. INTRODUCTION

In North America, there is both a growing public fascination and a concern with genetic testing in relation to insurance. "Insurers press for genetic data" reads one newspaper title.[1] "Should bad genes rob you of life or health insurance?" inquires another article in the Toronto Star.[2] "No insurance company in Canada uses saliva samples to test DNA, Sandy Lowden says"[3] in response to what the insurance industry no doubt feels is mounting hyperbole.

However, in the next five to ten years, scientific developments are likely to make genetic information increasingly important and available to insurers. Genetic testing will become commonplace in the office of the medical practitioner. "These techniques have already shown that genetic mutations can affect susceptibility to heart disease, lung, breast and colon cancer, insulin-dependent diabetes, and Alzheimer disease. In the near future, genetic testing is likely to be available for risk of colon cancer and for breast cancer as well. Additionally, we may see genetic risk assessment for some forms of heart disease, neurodegenerative disorders, and early onset dementias."[4] As costs of genetic testing decrease, expanded screening programs for newborns, for carrier status prior to reproduction, and for non-invasive fetal screening of maternal blood may well become part of public health prevention programs under Canada's national health insurance system. It is still questionable whether this "at risk" genetic information will become routine for insurance purposes (like family histories are now) and simply be factored in.

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1 *The Toronto Star* (December 29, 1993) B1.

2 *The Toronto Star* (September 15, 1991) B6.

3 *The Globe and Mail* (July 21, 1994) Fifth Column Feedback, A20 written in response to "Genetic research has a history of lousy social policy, Douglas Powell says" in the Globe and Mail (July 12, 1994) Fifth Column Feedback, A18.

4 NIH-DOE Working Group on Ethical, Legal and Social Implications of Human Genome Research, *Genetic Information and Health Insurance* (*Report of the Task Force on Genetic Information and Insurance*) (Washington, DC: Human Genome Project, NIH Pub. No. 93-3686, 1993) at 12. (hereinafter *Task Force on Genetic Information and Insurance*).

Both the Royal Commission on New Reproductive Technologies[5] and the Science Council of Canada[6] saw the area of genetics and insurance as being one meriting national review. The larger social and public issues surrounding potential genetic discrimination make reported cases of alleged discrimination particularly revealing of future trends.[7] Yet, in a 1992 OTA survey, "a majority of [insurers] reported they thought it "somewhat unlikely" or "very unlikely" that they would be using genetic information for underwriting".[8]

However, many contend that, as genetic information becomes an integral part of medical care, boundaries between genetic and nongenetic conditions will become increasingly unclear,[9] and that to the extent that genetic information is contained in medical records and family histories it will be included in legitimate risk assessment discrimination. The United States National Center for Human Genome Research stated that "[f]or policy purposes, it will become increasingly difficult to distinguish genetic from nongenetic diseases, and genetic information from nongenetic information" and goes on to observe that "[r]ecognizing that our genes affect many common diseases not previously thought of as genetic will transform the scope and meaning of terms such as genetic information, genetic test, asymptomatic condition, presymptomatic condition, and genetic predisposition to disease".[10] Should insurers be asked to ignore all this information simply because it is genetic in nature?

Additional questions abound: What is "legitimate" discrimination? How far can insurers go to obtain genetic information? Further, in the current Canadian social security and health context, might we not consider access to and availability of a basic minimum of life insurance as an entitlement, rather than simply as a privilege since it is often a prerequisite for other

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5 Royal Commission on New Reproductive Technologies, *Proceed with Care,* Vol. 2 (Ottawa: Minister of Government Services Canada, 1992) at 870.

6 Science Council of Canada, *Genetics in Canadian Health Care*, Report 42 (Ottawa: Minister of Supply and Services Canada, 1991).

7 P. Billings, as cited in L. Gostin, "Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers" (1991) 17 Am. J. Law & Med. 109 at 118-119; P.R. Billings, M.A. Kohn et al., "Discrimination as a Consequence of Genetic Testing" (1992) 50:3 Am. J. Hum. Genet. 476 at 482.

8 U.S. Congress, Office of Technology Assessment, *Genetic Tests and Health Insurance*: *Results of a Survey—Background Paper*, OTA-BP-BA-98 (Washington, DC: U.S. Government Printing Office, October 1992) at 35.

9 See R. Pokorski, "Genetic Information and Life Insurance" (1995) 376 Nature 13; ASHG Ad Hoc Committee on Insurance Issues in Genetic Testing, "Background Statement: Genetic Testing and Insurance" (1995) 56 Am. J. Hum. Genet. 327 and Sandberg, "Genetic Information and Life Insurance: A Proposal for an Ethical European Policy" (1995) 40 (11) Soc. Sci. Med. 1549 at 1550, who, as an example, notes that cancer is seen as a result of multiple genetic changes which may be inherited or caused by environmental factors or random mutation. Therefore it is neither responsible nor accurate to refer to cancer as simply genetic or non-genetic. Cancer and other diseases will come to be seen as the outcome of a complex set of interactions of both genetic and non-genetic factors.

10 See *supra*, note 4, and Pokorski, *ibid.*, at 13.

economic "goods" such as credit, mortgages and so on?[11] Such an approach is already under consideration in Europe.[12]

A brief overview of the international, regional, and national policies and recommendations outside of Canada will be useful in determining what role genetic testing and information will, and ultimately should, play in insurance. Internationally, the World Medical Association[13] adopted a position against any testing by insurers or asking specific questions about the results of genetic tests.

Similarly, in a 1989 resolution on the ethical and legal problems of genetic engineering, the European Parliament maintained that insurance companies should have no right to demand genetic testing before or after the conclusion of an insurance contract; nor should they have the right to be informed of any earlier test results; genetic analysis should not be a requirement for the conclusion of an insurance contract; and furthermore, insurers have no right to be notified by the policy-holder of all the genetic data known to the latter.[14] The European Parliament therefore favours a complete ban on the use of genetic testing in insurance matters.[15] In 1992, the Council of Europe also issued a recommendation on genetic testing and screening for health care purposes. The recommendation stated that insurers should not have the right to require genetic testing as a pre-condition for the conclusion or modification of an insurance contract.[16]

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11 B. M. Knoppers "Panel on Legal Issues in Genetic Testing" (1993) 25:2 J. of Ins. Med. (Suppl. B) 263.

12 Most countries have a social security and health care system largely similar to Canada's.

13 World Medical Association, *Declaration on the Human Genome Project*, adopted by the 44th World Medical Assembly, Marbella, Spain, September 1992 at 2.

14 European Parliament, "Resolution on the Ethical and Legal Problems of Genetic Engineering" (March 16, 1989) in *Ethical and Legal Problems of Genetic Engineering and Human Artificial Insemination*, Committee on Legal Affairs and Citizen's Rights, (Luxembourg: Office for Official Publications of the European Communities, 1990), principles 19 and 20 at 13-14.

15 See Sandberg, *supra*, note 9, at 1550-3 who points out that the European Parliament's claim that insurer's should not have the right to require genetic testing or to inquire about results of previously performed tests has not been raised with respect to other kinds of medical risk information, implicitly indicating that genetic information is relevantly different from all other medical information and thus should be treated differently. The author further compares genetic information with HIV information and notes that the latter is not accorded special status but rather is accepted just as other medical risk information. Sandberg maintains that there are no morally relevant reasons for excepting genetic information and not HIV information and that there is therefore no reason to give genetic information special status compared to other medical information.

16 Council of Europe, C.M., 470th meeting, Recommendation on Genetic Testing and Screening for Health Care Purposes, *Adopted*, R(92)3 Princ. 7 C.II. The Explanatory Memorandum states that it is desirable to extend the protection of a person's private life, concerning in particular genetic data which are very valuable, to the field of activity of insurance companies, within the limits of insurance law. Principle 7 should not be subject to any derogation since neither the protection of the health of the person concerned nor that of a third party is at stake, but only the insurance companies' own interests. See also the Sandberg argument, *ibid.*, which equally applies to the Council of Europe.

On a European national level, France, in a statement of its national ethics committee, asked that legislation be introduced prohibiting access by insurers to genetic information in registries or banks, or even to ask for authorization to access the medical file.[17] In April 1994, prior to any legislative action, the French insurance industry, however, adopted a voluntary moratorium.[18]

Germany, in a resolution of the Conference of Data commissioners in the Federal Republic of Germany in 1989, maintained that gene analysis in the insurance industry is irreconcilable with the basic principle of insurance, that is, to cover rather than to exclude risks. The Commissioners foresaw the need for a clause in the law covering insurance contracts, specifically prohibiting gene analysis. They suggested that there be no access to medical files for genetic information. Yet, they conceded that if at the time of contract the applicant has knowledge of a serious genetic disorder, then it should be revealed and the interest of the insurer is legitimate.[19]

According to a report issued by a committee of the Health Council of the Netherlands, access to basic health and life insurance, and the social security system in general, must remain open to all. The Council recommended prohibition on the use of genetic testing in connection with access to life and disability insurance and to personal pension plans. It urged legislative restrictions on the rights of insurers to require disclosure of known genetic information on individuals or family members, as long as the coverage sought is below the ceiling appropriate to the applicants' social and financial circumstances.[20] In November 1990, Dutch insurers adopted a self-imposed five-year moratorium on the use of genetic information.

In Denmark, on April 25, 1991, Parliament resolved to ban the use of genetic testing for the purposes of employment, pensions, and insurance. The Minister of Employment was asked to draft a bill. Legislation was adopted and was to have been enacted but surprisingly was opposed by the trade unions who saw some usefulness in genetic monitoring.[21]

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17 Comité consultatif national d'éthique (France) pour les sciences de la vie et de la santé, "Application des tests génétiques aux études individuelles, études familiales et études de populations" (1991) 7 Médecine-Sciences 842. This approach was adopted in the Civil Code of Beliguim in 1992 Article 95 de la loi 25-6-92, sur le contrat d'assurance terrestre. M.B., 20-8-92; 18283-18333.

18 See article in *Le Monde*, "Pendant cinq ans, les assureurs n'auront pas recours aux informations fournies par les tests génétiques" (8 avril 1994) B11.

19 Resolution of the Conference of the Data Protection Commissioners of the Federal Republic of Germany, October 26-27, 1989.

20 Health Council of the Netherlands, *Heredity: Science and Society* (The Hague: H.C.N., 1989) at 139-140. Note that at coverage levels above the ceiling, the obligation to disclose relevant information would be retained. Also Sandberg, *supra*, note 9, at 1549 who advocates a regime of limited community-rated private life insurance as proposed by the Dutch Committee. See *infra,* note 119.

21 A bill on a law prohibiting the use of genetic tests in the appointments and in the subscription of pensions and insurance policies, as discussed in *4th Annual Report of the Danish Council of Ethics 1991*

In December 1993, recognizing that, for most people, "life insurance is normally linked to home purchase and the covering of basic family responsibilities",[22] the Nuffield Council on Bioethics recommended that "British insurance companies should adhere to their current policy of not requiring any genetic tests as a prerequisite of obtaining insurance".[23] It also maintained that "there should be early discussions between the Government and the British insurance industry about the future use of genetic data, and that pending the outcome, the companies should accept a temporary moratorium on requiring the disclosure of genetic data".[24] In 1995, the House of Commons Select Committee on Science and Technology recommended that the insurance industry be allowed one year in which to propose a solution regarding the use of genetic information in insurance that would be acceptable to Parliament, and that if it fails to do so, a solution should be sought, by legislation if necessary.[25]

In the American context, in 1993, a report of an NIH-DOE task force on genetic information and insurance recommended, with regard to genetic testing for health coverage, that "[u]ntil participation in a program of basic health services is universal, alternative means of reducing the risk of genetic discrimination should be developed. As one step, health insurers should consider a moratorium on the use of genetic tests in underwriting. In addition, insurers could undertake vigorous educational efforts within the industry to improve the understanding of genetic information."[26] The Task Force did not study life or disability insurance, which are of more concern to Canadians, but recognized that life and disability insurance involve individual risk classification and "require examination in the context of burgeoning genetic information".[27] Moreover, at the close of 1995, eight states enacted some form of protection against genetic discrimination in health insurance, thereby prohibiting

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(Copenhagen: Danish Council of Ethics, 1992) at 11-13; J. Hodgson, "Denmark Bans Use of Testing Info" (1991) 9 Biotechnology 508.

22 Nuffield Council on Bioethics, *Genetic Screening: Ethical Issues* (London: N.C.B.,1993) at 67.

23 *Ibid.*, at 73.

24 *Ibid.*

25 House of Commons Select Committee on Science and Technology, *Human Genetics: The Science and its Consequences*, Third Report of the Science and Technology Committee 1994-1995, 6 July 1995, at para 248. The Committee noted the ABI's (Association of British Insurers) complacency regarding the future use of genetic information in insurance, the ABI being of the opinion that use of such information will be limited, at para 247. See "Insurers Quizzed Over Use of Genetic Testing," *Guardian*, 20 May 1995, p.29; C. Merrell, "Fears over Genetic Testing", (October 8, 1995) The Observer. Also see, D. Dickson, "U.K. to Set up Advisory Panel on Genetic Data" (1995) 375 Nature 714 who notes that a national advisory committee to provide government ministers with advice on how they should regulate the use of genetic information is likely to be set up in Britain and will be welcomed by those particularly concerned about the pressures that the availability of genetic information will inevitably place on insurance companies in setting life and health insurance premiums; and D. Dickson, "Royal Society Plans Genetics Meeting with Actuarial Profession", (1995) 377 Nature 375 who describes a proposed joint meeting of the Royal Society and the actuarial profession which will attempt to help the insurance industry assess the health prospects of individuals on the basis of knowledge of their genetic make-up.

26 *Task Force on Genetic Information and Insurance*, *supra*, note 4, at 29.

27 *Ibid.*

insurers from denying coverage on the basis of genetic test results and using this information to establish premiums, charge differential rates, or limit benefits.[28]

In Canada, in a study paper for the Law Reform Commission of Canada,[29] it was suggested that basic life insurance for all applicants with "no questions asked" could provide minimum coverage to everyone and avoid problems of discrimination. Further, it recommended that additional coverage above "basic coverage for all" could be dependent on an agreement by the applicant to be tested for genetic disorders.[30] The Science Council of Canada made the same suggestion in its 1991 report and recommended that some form of basic insurance be universally available at the same premium, with additional insurance optional and contingent upon genetic information provided by the applicant.[31]

Generally then, proposed "genetic specific" legislation in Europe would restrict if not totally ban insurers from testing for, using, or having access to, genetic information (and this in countries with national health care schemes like Canada). In short, irrespective of the structure of the insurance system in a given country, or whether—as is often the case with health insurance in the United States—it is obtained through group insurance via employers who are often self-insured or through an individual application for life or disability insurance, direct genetic testing or access to genetic information in medical records by insurers raises significant policy issues.

Since an understanding of the goals and practices of the insurance industry is of fundamental importance, we will first examine pertinent general insurance principles, such as information gathering, risk selection and classification. We will then consider these principles within the legislative framework of the Ontario *Insurance Act* and the *Human Rights Code.* Finally, we will turn to a brief consideration of privacy and confidentiality, since use of genetic information raises particular concerns within the insurance industry.

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28 K.L. Hudson, K.H. Rothenberg, L.B. Andrews et.al., "Genetic Discrimination and Health Insurance: An Urgent Need for Reform", (1995) 270 Science 391. Nearly all of the state laws focus narrowly on genetic tests rather than more broadly on genetic information generated by family history, physical examination or the medical record. Oregon and California integrate protection against discrimination in insurance practices with privacy protections that prohibit insurers from requesting genetic information and from disclosing genetic information without authorization (at 392). See also K.H. Rothenberg, "Genetic Information and Health Insurance: State Legislative Approaches", (1995) 23 Journal of Law, Medicine & Ethics 312-19.

29 B.M. Knoppers, *Human Dignity and Genetic Heritage*, (Ottawa: Law Reform Commission of Canada, 1991). Note that the author now refined her position and considers a "no questions asked" policy when the amount of insurance requested is proportionate to the income level of the applicant to be a more equitable and attractive alternative (for both applicants and the insurance industry) than simply allowing a minimal amount of life insurance. This alternative is very much in line with the Dutch solution, *infr*a, note 20, and was further advocated by Sandberg, *supra*, note 9.

30 *Ibid.*, at 50 and 63.

31 Science Council of Canada, *supra*, note 6, at 77-80.

2. THE INSURANCE INDUSTRY

The insurance industry in Canada is North American and, as such, other than with respect to health insurance, American studies and statistics on genetic testing and insurance provide a window onto the actual situation—"amidst the rhetoric and anecdotal stories".[32] Access to medical information is crucial, and were there to be restraints on the full disclosure of information, insurers are particularly concerned about adverse selection.

(a) CURRENT PRACTICES

Over ninety-seven percent of applications for life insurance are currently accepted. Only three percent who apply for coverage are denied.[33] What is not known, however, is whether introducing genetic testing into the underwriting process[34] will affect this rate of acceptance. In 1988, one government study on medical testing and health insurance wrote: [35]

> Genetic tests in their present state are impractical to administer, require considerable technical skills, may require analyses of multiple family members, are expensive to perform, and are currently available for only a small number of relatively rare diseases. Thus it appears that in the near future, they will not directly be used in the insurance underwriting process. However, as genetic tests become increasingly available and used by clinicians, results from these tests will become part of the medical records of their patients. Applicants will therefore have to acknowledge their existence.

Three years later an industry study specific to the issue of genetic testing concluded "that genetic information [is] as potentially relevant to risk classification as any other medical information. The ACLI and the HIAA should continue to aggressively defend their member companies' need to have access to and consider any relevant health information for underwriting purposes, including genetic test information."[36] This study also found that no direct testing was being undertaken currently by the industry, primarily due to costs.[37]

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32 The American Council of Life Insurance and the Health Insurance Association of America, *Report of the ACLI-HIAA Task Force on Genetic Testing* (Washington, DC: 1991) at 5. (hereinafter *Report of ACLI-HIAA Task Force*)

33 *Ibid.*

34 Underwriting is the process whereby insurers evaluate the risk that an individual applying for insurance presents and adjust their premium tc acknowledge that risk.

35 U. S. Congress, Office of Technology Assessment, *Medical Testing and Health Insurance (Summary)*, OTA-H-384 (Washington, DC: U.S. Government Printing Office, 1988) at 17.

36 *Report of ACLI-HIAA Task Force*, *supra,* note 32, at 10.

37 *Ibid.*: "The test for Huntington's disease, for example, costs thousands of dollars. Though costs may come down over time (a cystic fibrosis test now exists for about $200) it will be years and perhaps decades before insurers could realistically afford genetic testing on any wide-scale basis." See also ASHG Ad Hoc Committee, *supra*, note 9, at 329 who point out that while that the rarity of genetic testing is due to the high cost of testing and unfamiliarity with their usefulness and validity in the insurance setting, "multiplexing" of tests could result in marked reduction of cost, making genetic testing as commonplace as multiple tests on a urine sample; and R. Pokorski, *supra*, note 9, at 13 who notes that the U.S. Institute of Medicine's

Moreover, although insurers may not now require genetic testing, they nevertheless make decisions based on genetic information since of the 6,000 genetic disorders and diseases identified, predispositions to many of these diseases are already detectable to some extent through family histories. These standardized family history questionnaires can reveal predispositions to diseases such as heart disease, Alzheimer, and some cancers and are already factored into the underwriting process. As summarized in a 1992 OTA study, "it is less expensive to ask a question or request medical records [than to test], and applicants disclose genetic information as part of the battery of questions they respond to in personal and family history inquiries".[38] It is through access to medical records that genetic information will be obtained.[39]

Because the business of insurance is economically impractical if there is a substantial probability that the presumed risk will occur, that is, that the event is equivalent to a certainty, insurers cannot contract to assume every risk. In life insurance, although death is certain, the time of its occurrence is not, and it is against the occurrence of death sooner rather than later that insurance is obtained. Therefore, using statistics on mortality and morbidity, an insurance company attempts to determine with whom it can contract and at what cost it can provide protection, in order to select the particular risks that will be assumed. Insurance is based on the sharing of all known risks among a class of insureds (solidarity). This classification is based on actuarial data of mortality, morbidity, and risk established according to employment, lifestyle, socio-economic, environmental, demographic, and medical data, amongst others.[40]

Insurance refers to the notion of forming a risk pool in which each of the members participate according to the risk they represent to the pool. The risk of death of an insured will be supported by the totality of the insureds, each having contributed to the risk pool in proportion to the probability of their own death. The cost of the risk insured is thus distributed between the members of the pool, each paying his own part. This is commutative justice. For insurance purposes, equality means equal treatment for equals not equal treatment for all. Insurers thus assert that it is necessary to segregate insureds with identifiable health

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Committee on Assessing Genetic Risks predicts that "multiplex genetic testing" will soon become routine clinical practice, with many tests done on a sample of blood or other tissue.

38 *Supra,* note 8, at 33. Also, see Privacy Commissioner of Canada, *Genetic Testing and Privacy* (Ottawa: Minister of Supplies and Services of Canada, 1992) at 20,which states that "[t]he Canadian insurance industry apparently does not require insurance applicants to undergo genetic testing at present. However, the industry considers it appropriate that persons aware of genetic abnormalities which may affect their insurability disclose this when applying for insurance." The report does point out that it may be "argued that insurance companies already do a crude form of genetic "screening" by asking insurance applicants to provide a family health history."

39 See *infra,* ch. 9. It is unlikely that genetic information can be segregated from one's medical record, and even if it could, much of the information about risk factors, diseases, diagnostic tests and treatment will in fact reveal genetic information. See also, P. Reilly, "Conference Summary", (1993) 25 J. Ins. Med. (supplement B) 298.

40 See Knoppers, *supra,* note 11.

risks from those without health risks.[41] Failure to separate individuals with different degrees of risk will affect the insurance principle of equity.[42] As a result, the healthy would be overcharged or treated unfairly, and would ultimately choose not to buy new or further coverage. Therefore, in principle, insurers maintain that they must refuse to cover a risk that is too high rather than making the pool support this increased risk. In this manner, the rule that the risk of loss shall be shared equally is maintained (equity).[43]

The most fundamental difference between individual and group insurance is in underwriting. Genetic testing for the purposes of obtaining insurance arises primarily in obtaining individual as opposed to group, health or life insurance. For an individual to purchase an individual health or life insurance policy, at specified premiums and conditions, the insurance company must be able to determine what risk the insured has of suffering an insured event. Medical information, which could include genetic test results, would be used by insurers to determine whether an individual's risk exceeds that expected for other persons of the same age. Premiums are commensurate with risks. When risks are too high, insurance will not be sold.[44]

People who have group insurance do not usually have to provide medical information once they are in a group (unless the group has fewer than ten people or late entrants). The amount the group pays for insurance is based on the risks of insured events experienced by people like those in the group ("experience-related"). This situation typically refers to persons who receive health and/or life insurance through their employers.[45] While these policies are generally not underwritten, where an applicant wishes to have more coverage than others in the group or wishes to join the group following a refusal to do so after a defined period of employment, medical testing will be required as the insurer may experience adverse selection.

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41 K.A. Clifford and R.P. Iuculano, "AIDS and Insurance: The Rationale for AIDS-Related Testing" (1987) 100:7 Harvard Law Review 1806 at 1811.

42 *Ibid.*

43 B.A. Christensen, "The Insurance Industry Requests the Right to Use the AIDS Antibody Test as an Underwriting Factor" (1987) 126:8 Trusts and Estates 58 at 59.

44 N.A. Holtzman, *Proceed with Caution* (Baltimore: Johns Hopkins University Press, 1989) at 193.

45 See *infra*, ch. 7 and more specifically, J.D. Hammond and A.F. Shapiro, "AIDS and the Limits of Insurability" (1986) 64:1 The Milbank Quarterly 143 at 162-165; K.A. Clifford and R.P. Iuculano, *supra*, note 40 and Holtzman, *ibid.*, at 193-194.

(b) ADVERSE SELECTION

It is interesting to note that "insurers may be more fearful of genetic testing than are consumers".[46] This is because the very aim of underwriting is to identify people at increased risk. Adverse selection or "anti-selection" is the abusive purchase of insurance by persons with poorer than average health expectations and who are higher risks than their insurers are aware.[47] While as shown above, direct genetic testing by insurers remains speculative, genetic testing and information will increasingly be found in the physician-patient relationship making the applicant privy to information that the insurer does not have. A recent survey found that insurers were less concerned about genetic testing as a means to improve risk selection than about "the potential for adverse selection if insurers were ever denied access to the results of genetic tests already known to the applicant.... Simply put, if insurers are denied access to genetic test results, the amount paid out in insurance claims could increase substantially and the result would be higher premiums for most policy-holders."[48] As a result, companies that require genetic information will be able to differentiate in offering lower premiums, while companies that do not require such information will attract at-risk individuals and pay out higher premiums and suffer greater losses. To avoid this anti-selection, insurance companies may protect themselves in three ways.

First, insurers can legitimately provide a time frame (usually two years)[49] within which fraudulent misrepresentation or concealment of pre-existing conditions allows the insurer to void the contract. Pre-existing conditions are those that have or will impair the applicant's health to some degree. If the pre-existing condition is genetic and indicates that the applicant will develop a disease, it is possible that underwriters could cancel the policy if this result is discovered within the two-year period indicated. Whether such a cancellation would be upheld in court might depend on the applicants' knowledge at the time of application as well

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46 *Report of ACLI-HIAA Task Force*, *supra*, note 32, at 8.

47 *Ibid.*, See also Clifford and Iuculano, *supra,* note 41, at 1817.

48 Report, *ibid.* For example, an individual who undergoes genetic testing revealing a genetic disease or a propensity toward a genetic disease is more likely to apply for insurance or apply for a greater amount of insurance because the applicant knows a claim may be likely in the future. If the insurer is not permitted to perform genetic tests, or ask the applicant or his attending physician for the results of previous testing, adverse selection could occur and force the insurer to charge a premium unrelated to the actual risk. See M.E. Brom, "Insurers and Genetic Testing: Shopping For That Perfect Pair of Genes" (1991) 40 Drake Law Review 121 at 134-5. See H. Nys et al., "Predictive Genetic Information and Life Insurance: Legal Aspects. Towards European Community Policy?" (1993) Maastricht: Rijksuniversiteit Limburg, Vakgroep Gezondheidsrecht at 19, who notes that the scenario of individuals with no known family history having such a risk identified by a battery of genetic tests and then taking out high levels of insurance is a currently unrealistic proposition. Of more immediate concern is the applicant with known family risk of a serious disease who is already largely disbarred from insurance and has little likelihood of obtaining excessive coverage. The existence of an undisclosed high risk will be largely irrelevant, and as such, adverse selection in such a context is of little consequence - an interesting conclusion given that the majority of genetic tests are currently being done within the framework of family risk.

49 *Insurance Act*, R.S.O. 1990, c. I.8., s. 184(2).

as the predictive value of the test in question.[50] Thus the availability of insurance may well be affected by the definition accorded the term "preexisting conditions". A person found to be carrying a gene, even though asymptomatic until late life, may be considered to have had the "condition" since birth, or closer to the common understanding of the term, a disease may be preexisting only if it was a previously diagnosed or treated condition.[51]

Second, the underwriter will determine if other insurance companies have information on the applicant that it does not have, typically through the Medical Information Bureau (MIB), a database of insurance applicants identified by name, date, and place of birth. A series of codes[52] describes broad classes of medical impairments with qualifying dates and sources of information included in each file. Access to such information protects against fraud and makes available significant medical findings and test results. The applicant's authorization for the insurance company to use MIB is part of a completed application for coverage. Insurers can access the databank only to confirm that they have reviewed the same medical history of the applicant that has been collected by their competitors. The information cannot be used directly to rate or deny insurance to an applicant. If the application does not contain all the information that appears on the MIB files, the underwriter is alerted to the possibility of missed information and will typically request further investigation. Although the MIB currently does not collect or store genetic data, should a highly predictive test become available, serious consideration would likely be given to using the results in the underwriting process.[53]

Third, the insurance company can use predictive tests,[54] or request the results of such tests if they have been performed elsewhere, to avoid anti-selection. By excluding people on the basis of a test,[55] a company can lower its standard premium and gain a competitive

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50 See the Quebec case of *Audet* c. *L' Industriellle-Alliance* [1990] R.R.A. 500 (C.S.).

51 See ASHG Ad Hoc Committee, *supra*, note 9, at 329. Note that life insurance policies do not exclude coverage for preexisting conditions. Therefore, in the absence of such a clause insurers would not be permitted to void a contract by arguing that the insured had a preexisting condition at the time of underwriting provided the applicant was unaware of the condition at the time.

52 Although many diseases are genetic or have a genetic component, MIB codes include only a few genetic diseases, for example, cystic fibrosis and hemophilia. Other diseases are generally coded under obscure general categories. Further, there is no list for heterozygotes for recessively inherited conditions.

53 The Medical Information Bureau is a consortium of 750 North American insurance companies. See M.A. Rothstein, "Genetics, Insurance and the Ethics of Genetic Counseling"(1993) 3 Molecular Genet. Med. 159.

54 See Sandberg, *supra*, note 9, at 1555 who argues that there is no ground for allowing insurers to require applicants to undergo genetic tests not previously taken on the basis of adverse selection fears since without such information, both parties would be in a situation of reciprocal uncertainty about the genetic characteristic(s) in question. Where both parties lack the information there is no basis for adverse selection. See also, J.S. Alper and M.R. Natowicz, "Genetic Testing and Insurance" (1993) 307 B.M.J. 1506.

55 Genetic testing can identify individuals with 3 types of genetic conditions: (1) individuals who currently have or are certain to develop a genetic disease directly attributable to a specific chromosomal or gene defect, such as Huntington disease, cystic fibrosis, or Duchenne muscular dystrophy; (2) individuals who do not possess a genetic disease but are carriers of a disease and as such may pass the defective gene on to their children, for example, Tay-Sachs and sickle cell anemia; and (3) individuals with a genetic predisposition to

advantage. Individuals who test positive will turn to companies that do not use the test and will succeed in getting insurance at the standard premium. This financially endangers the latter companies, which will pay out in claims a higher proportion of their premiums than expected as the individuals suffer events at greater than the expected rate. To avoid this, once one insurance company adopts predictive tests for underwriting purposes, other companies are likely to follow suit.[56]

What should be remembered, however, is that while medical information has long been the "stock in trade" of risk classification and selection and, in all likelihood, persons *affected* with single gene disorders will be classified along with other ill persons, most genetic information is and will be probabilistic and predictive in nature. Whether or when a genetic disorder will appear, and the intensity or the effect of individual lifestyle, occupation, and environment, are all unknown. Paradoxically, knowledge of increased risk may even serve to provide the individual with lifestyle, occupation, or reproductive choices that could make the candidate a better insurance risk. Furthermore, while some conditions have a purely genetic basis, most genetic disorders, even single gene disorders, involve an interaction between genetic predisposition and environmental factors.[57] Finally, many diseases run along familial lines and by populations, regions, or cultural groups, thus raising the question of discrimination and risk selection by perception and "association".[58] These factors, to say nothing of the confidentiality concerns surrounding the possession by insurance companies of highly sensitive information, make the legal framework extremely important.

3. LEGAL FRAMEWORK

According to Black's Law Dictionary, insurance is "a private contract in which one party, the insured, transfers certain risks of loss to another, the insurer, for monetary consideration". The concept of risk is central to the contract of insurance and the essence of risk is uncertainty. The purpose of insurance is to minimize financial losses that may arise from unexpected events. In short, "insurance is a contract upon speculation".[59]

Section 5 of the *Canadian Human Rights Act* [60] prohibits discrimination with respect to services customarily available to the general public. However, it grants the insurance industry

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disease in the future who may or may not develop the disease and whose occurrence may well be affected by environmental factors, for example, cancer and coronary heart disease. See Brom, *supra*, note 48, at 123-4.

56 Rothstein, *supra,* note 53.

57 Note that most genetic defects that cause disease in later life are probably not inherited but are acquired as somatic mutations, that is, mutations acquired later in life through exposure to environmental carcinogens or errors in DNA replication or repair. See Pokorski, *supra*, note 9, at 14.

58 On the subject of the nature and confidentiality of genetic information, see *infra,* ch. 9.

59 *Carter* v. *Boehm* (1766) 3 Burr. 1905 (K.B.). Based on a concept of a risk continuum, at some point a combination of factors will render a future event certain in the eyes of the law and thus deprive it of its insurable nature. J. Nicholl, "Courting the Risk in Insurance Law" (1988) 48(2) R. du B. 175.

60 *Canadian Human Rights Act*, R.S.C. 1985, c. H-6.

an exemption under section 22.[61] Generally, differentiation in the amounts of benefits payable or in the rates of contribution to a plan do not constitute the basis for a complaint where made on an actuarial basis.[62] Insurers assert that differentiation, particularly where individual or small group policies are concerned, is at the heart of commercial insurance, since premiums are based on differences in expected mortality rates. Differentiation on the basis of health risks must be distinguished from jeopardizing basic rights; arguably they are necessary for actuaries to determine how much premium to collect to pay for future claims. Others argue, however, that "actuarial fairness is neither a necessary nor a sufficient condition for moral fairness or justice in an insurance scheme... [This] link presupposes that individuals are entitled to benefit from any of their individual differences, especially their different risks for disease and disability."[63]

In Ontario, the *Insurance Act* [64] provides very little direct guidance as to what forms of discrimination are acceptable in the insurance industry. Section 47(2) of the Ontario *Human Rights Code*[65] provides that it prevails over other Acts, and its provisions apply to the vast majority of insurance contracts in Ontario. An examination of this legislation and its interpretation in the insurance contract is necessary in order to circumscribe legitimate discrimination and, in the event of the receipt and storage of such information, to understand the special confidentiality concerns it raises for the industry.

(a) THE INSURANCE ACT

The characteristics by which insurance applicants are categorized is decided mainly by the market-oriented judgments of the insurance companies, judgments that are subject to the approval of the Ontario Insurance Commission. The Commission is charged with very broad regulatory jurisdiction to "administer and enforce this Act and to supervise generally...the business of insurance in Ontario".[66] More specifically, under section 117(2) of the Act, "[t]he Superintendent shall report to the Commissioner any case where an insurer issues a policy or uses an application that, in the opinion of the Superintendent, is unfair, fraudulent or not in the public interest". Indeed, according to that section of the Act, the Commissioner may, if he concurs with the report, prohibit the insurer from issuing such a form of policy or application. These considerable powers however must be placed in the context "of a working philosophy

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61 *Ibid.*

62 *Canadian Human Rights Benefit Regulations,* SOR/80-68, s. 2(1) and limitations of the applicability of the *Canadian Human Rights Act, supra,* note 60.

63 N. Daniels, "*Insurability and the HIV Epidemic: Ethical Issues in Underwriting*" (1990) 68:4 Milbank Quarterly 497 at 504.

64 *Insurance Act, supra,* note 49.

65 *Ontario Human Rights Code*, R.S.O. 1990, c. H.19.

66 *Insurance Act, supra,* note 49, s. 2(3).

of mutual cooperation rather than confrontation between the industry and the Superintendent".[67]

The Act also governs the licensing of insurance companies, and indirectly controls the characteristics of selection in life insurance by specifically approving certain "tables of mortality" for use in the industry. With respect to life insurance specifically, the insurer must set forth in either individual or group policies "the method of determining the amount of the insurance money payable", but makes no reference to the validity of the method employed (sections 175(2) and 176). The applicant has the duty to disclose any fact that is material to the insurance. This includes the results of medical examinations (section 183). Similar provisions govern accident and sickness insurance with the specific mention of adjustment of premiums payable according to the physical health or age of the applicant (sections 311 and 312). These two characteristics therefore seem to be approved as acceptable forms of discrimination under the Act. The one final control over insurance practices in Ontario found in section 439, which applies to all insurance contracts, is the prohibition of "unfair or deceptive acts or practices" (section 438).[68] Recently, the Supreme Court of Canada considered this latter section and found that discrimination on the basis of age, sex, and marital status in auto insurance was reasonable.[69]

In short, on the basis of this Act alone, it is clear that, at face value, risk classification, selection, or even denial of insurance for extreme risk applicants, is sanctioned by law, and the presence of genetic disease, or predisposition or susceptibility to genetic disease, could theoretically simply be "factored in" as any other type of information. This will in all likelihood be accomplished not only by the standard questionnaires but by requesting access to the applicants' medical files. Can genetic risks simply be redistributed like any other misfortune or are they so inherent to the person like race, handicap or sex that to do so would be discriminatory under the *Human Rights Code* ?

(b) THE HUMAN RIGHTS CODE

Recourse to human rights legislation for insurance discrimination is necessary for a number of reasons: an applicant cannot proceed in a civil action against an insurer, as the Supreme Court of Canada has held that a common law tort of discrimination does not exist in Canada;[70] provincial insurance legislation does not prohibit the use of genetic data in

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67 *Bates* v. *Zurich Insurance Company,* (1985), 6 C.H.R.R. D2948 at D2966 (hereinafter *Bates*).

68 *Insurance Act*, *supra,* note 49.

69 *Zurich Insurance Co.* v. *Ontario (Human Rights Commission)*, [1992] S.C.R. 321 (hereinafter *Zurich*).

70 *Board of Governors of Seneca College* v. *Bhadauria* (1981) 124 D.L.R. (3d) 193.

underwriting;[71] and the Canadian Charter cannot be invoked for contracts involving private activities.[72] Human rights legislation is therefore the only avenue available.

It is first necessary to determine whether genetic disease, predisposition, or susceptibility would be considered a prohibited ground of discrimination under the *Human Rights Code.* Human rights tribunals have given the definitions of handicap[73] and disability expansive interpretations, making it clear that the respondent's perception of the disability is the key to triggering protection from discrimination on the grounds of disability, whether such a disability exists or not.[74] Whether genetic disease, predisposition, or susceptibility would be considered a prohibited ground of discrimination,[75] and whether use of such data would be discriminatory in insurance underwriting as infringing upon an individual's right to equal treatment with respect to services and the right to contract on equal terms without discrimination,[76] would depend on whether the discrimination is reasonable and *bona fide.*[77]

As we have seen, all persons are simply at varying degrees of risk. Culture, environment, occupation, and lifestyle play an important role. What may be more important then is the fact that the *Code* and the Commission recognize the role of perception of difference as playing an equally discriminatory role in the social and economic sense. This is particularly important for persons who are predisposed to genetic conditions and who may never develop the disease. Even those carriers who are asymptomatic, (the "healthy ill"), may be so for many or most of their productive years.[78] Variability in expression and intensity

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71 *Insurance Act*, *supra*, note 49, s. 140.

72 Part 1 of the *Constitution Act*, 1982 being Schedule B of the *Canada Act*, 1982 (U.K.) c. 11.

73 *Ontario Human Rights Code, supra*, note 65, s. 10(1).

74 See *Foucault* v. *Canadian National Railways* (1981), 2 C.H.R.R. D475 (Interim Decision); (1981) 3 C.H.R.R. D677; *Fonatine* v. *Canadian Pacific Ltd.* (1989), 11 C.H.R.R. D288, aff'd (1990), 91 C.L.L.C. 17,0008 (Fed. C.A.). See N. Park and B. Dickens, "Legal and Ethical Issues in Genetic Prediction and Genetic Counselling for Breast, Ovarian and Colon Cancer Susceptibility" (1995) Critical Choices: Ethical, Legal and Social Behavioural Implications of Hereditable Breast, Ovarian and Colon Cancer (Background Papers, International Research and Policy Symposium, Toronto, April, 1995) 61 at 76.

75 Note that since 1985, the Ontario Human Rights Commission has recognized that AIDS falls under the prohibited grounds of handicap under the Code: Ontario Human Rights Commission, *Policy Statement on HIV/AIDS-Related Discrimination* (Toronto: OHRC, 1989). No such statement on genetic conditions has been made. While an analogy is often drawn between AIDS and genetic conditions, AIDS is acquired while genetic conditions are inherent to the person. This is not to say that the gene is the disease, that the person is the gene and that therefore, the person is the disease, but rather that the genetic patrimony or heritage is integral and in the absence of germ line therapy cannot be modified. See B.M. Knoppers, *supra,* note 29, at 16-17.

76 *Human Rights Code*, *supra*, note 65, ss. 1, 3, and 5(1).

77 *Ibid.,* s. 22. See, also, Dickens and Park, *supra*, note 74, at 76.

78 Note the distinction between being predisposed to disease—the disorder may or may not occur, and being asymptomatic—the condition is already present but the symptoms have not yet developed. Consider for example, the discovery of ApoE (apolipoprotein E) which is said to determine susceptibility to Alzheimer's disease: many people may develop the disease even though they do not carry the variant for gene, and many

may even make "affected" persons asymptomatic since the condition, when and if expressed, may actually be negligible in effect. According to popular perception, however, all of these persons or categories of persons would be considered as "having" the disease. Further, as genetics is familial, by virtue of "relationship" with an affected individual, other family members could also be considered at risk. The protections of the Code extend to such relationships (section 11). Therefore, as stated, unless actuarial data were sufficiently refined and sophisticated to differentiate between these categories, traditional classification practices could easily lead to discrimination unless the distinction, exclusion, or preference is reasonable and *bona fide*. The insurance company would have to establish the legitimacy of such practices through the presentation of statistical evidence.[79]

The *Zurich* case,[80] which concerned discrimination against a single male under the age of twenty-five in the field of automobile insurance, gave the courts an opportunity to consider what is *bona fide* and reasonable under the Code. By analogy, using the test developed in the *Etobicoke* case,[81] the board of inquiry held that the insurer should establish "that the very essence of its business would be undermined if it could no longer rely on discriminatory group characteristics for its rate classification system".[82] In concluding on this matter the Board held that "[t]here is simply no evidence, in my opinion, offered to support the assertion that it has been scientifically proven that there is a direct, causal relationship between the discriminatory group factors used - age, sex, and marital status and high risk".[83]

As in *Etobicoke,* the Board was not willing to allow stereotyping of social groups unless there was scientific evidence of its validity. Scientific or statistical evidence is apparently a fundamental requirement for the establishment of "reasonable and *bona fide*" under the Board's decision. The Board also made it quite clear that just because the industry had been using these discriminatory group factors for over fifty years did not in any way legitimate the practice.[84]

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people who have two copies of the gene may never develop the disease. See J. Webb, "Warning over Ambiguous Alzheimer's Test", (October, 1995) New Scientist 6.

79 J.E. McEwen, K. McCarty & P.R. Reilly, "Survey of Medical Directors of Life Insurance Companies Concerning Use of Genetic Information" (1993) 53 Am. J. Hum. Genet. 33 at 33. The authors found that "(3) many companies employ underwriting guidelines with respect to a variety of genetic conditions but do not always have their own detailed actuarial data on those conditions to support their rating decisions; (4) a considerable degree of subjectivity is involved in most insurers' rating decisions; and (5) some of the medical directors are not fully informed about basic principles of medical genetics."

80 *Zurich*, *supra*, note 69.

81 *Ontario Human Rights Commission* v. *Borough of Etobicoke,* [1982] 1 S.C.R. 202. (Hereinafter *Etobicoke*). The 2-pronged test encompassed a subjective element which verified that the discrimination had been imposed in good faith and with sincere intentions whereas the objective element examined whether the requirement was reasonably necessary to ensure efficient and economical performance of the job.

82 *Bates*, *supra*, note 67, at D/2965.

83 *Ibid.*

84 *Ibid.*, at D/2966.

The Supreme Court of Ontario overturned this decision,[85] which was subsequently affirmed by the Court of Appeal,[86] and the Supreme Court of Canada.[87] The appellate courts rejected the use of the *Etobicoke* test by the Board of Inquiry and lowered the stringency of the test substantially for deciding "reasonable and *bona fide*".[88]

The significant difference between the appeal decision and the original decision is that in the latter instance the court held that the onus lies on the insurance company to produce evidence of the statistical validity of the discrimination it wishes to employ. Thus insurance companies could propose what is "reasonable and *bona fide*" subject to adoption by the Insurance Superintendent's Committee. The Appeal Court did not want to challenge the categorization method chosen by the industry even though this position goes against many recent human rights decisions that demand that stereotypical notions about social groups be investigated directly for their validity and their impact.[89] The acceptability of the "reasonable and *bona fide*" distinction may nonetheless emerge because of the special context of genetics and insurance.

In summary, the lower court decisions provide two different approaches to the determination of what is a "reasonable and *bona fide*" distinction in the insurance industry. The difference between the two lies in both the stringency of the scientific data required to validate the distinction, and the onus that lies on the respective parties. In 1992, the Supreme Court of Canada upheld the position of the Appeal Court. However, in a dissenting opinion, Madam Justice L'Heureux-Dubé warned that "discrimination based on statistical correlation is simply discrimination in a more invidious form".[90] Such statistical proof "must not simply

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85 *Zurich v. Ontario (Human Rights Commission) and Bates* (1987) 8. C.H.R.R. D/4069.

86 *Zurich v. Ontario (Human Rights Commission)* (1989), 45 C.C.L.I. 303.

87 *Zurich, supra,* note 69.

88 See *Zurich* v. *Ontario* (*Human Rights Commission) and Bates*, *supra*, note 85, at D/4071:

> [I]n the course of its judgment the board progressed form (sic) the statutory requirement that the insurer show that it proceeded on 'reasonable and bona fide grounds' to a requirement that the insurer establish that its grounds were 'reasonably necessary'. After a consideration of American cases, it made a further leap to a requirement that the insurer establish 'that the very existence of the business would be undermined if the discriminatory requirements could not be relied upon'. In our view, neither of these leaps can be justified. Something may be reasonable without being necessary. Something may be reasonable without being so essential that the existence of an industry will be undermined if it cannot be relied upon.

See, also, *infra*, ch. 7.

89 For example, see *Etobicoke*, *supra,* note 81; *Andrews* v. *Law Society of British Columbia*, [1989] 1 S.C.R. 143 and L'Heureux-Dubé J. (diss.) in *Zurich*, *supra,* note 69, at 358: "the purpose of such [human rights] legislation is the protection of fundamental individual rights. These rights are violated if stereotypical group characteristics are ascribed to individuals. Since the protection of human rights is vitally important in our society, legislation prohibiting discrimination must be construed broadly using a purposive approach".

90 *Zurich, supra,* note 69, at 371.

be one of correlation, but one of causal connection".[91] Even though this was a minority position, according to the dissent, there is no doubt that the insurance industry has "too long relied upon the tradition of discriminatory practices in their industry in order to justify their refusal to take the first step in implementing a less discriminatory system".[92]

Currently, what is the impact of the Supreme Court of Canada's decision on the determination of "reasonable and *bona fide*" genetic discrimination? It should first be remembered that individuals not affected but simply "predisposed", fall into two groups.[93] The first group is affected by a small number of single gene disorders, such as Huntington disease, which have a virtual certainty of late onset. The second group may be affected by a much broader array of conditions that contribute to a high risk of suffering from a disease at some point in time.[94] While scientists continue to identify genetic risk factors, it is unlikely that most of these genes will be of sufficient predictive value for insurance purposes, although, through misinterpretation, they may be given unwarranted significance.

Should a more rigorous standard be applied, that is, should scientific proof establish that there is a direct, causal relationship between the discriminatory group factors used and high risk, then statistical evidence will have to be sufficiently rigorous to legitimate discrimination. Moreover, even if this test is met, according to the dissent of L'Heureux-Dubé J., the distinction, exclusion, and preference must be a reasonable means of identifying and classifying similar risks. Thus, the availability of alternative means of ascertaining risks must be measured. While the Board of Inquiry's requirement that the insurance industry show that it would be impractical or impossible to operate its business with the use of non-discriminatory criteria for rate classification, was too stringent, according to the dissent,[95]

> No human rights legislation could ever attain its objectives if discrimination could be justified by the self-serving claim that the practice 'has always been done this way', which is at the heart

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91 *Ibid.*: "The insurance industry simply does not know whether age, sex and marital status are causally connected to higher risk and is attempting to bridge the gap in its knowledge by reliance on myth and stereotype. This impressionistic approach does not satisfy the burden of proof and constitutes impermissible discrimination, in my view."

92 *Ibid.*, at 377-78.

93 G.W. de Wit, "Genetics: An Insurance Problem?" in Rigter et al. (eds), *The Social Consequences of Genetic Testing* (The Hague: Netherlands Scientific Council for Government Policy, 1990) 51, at 55-56.

94 Classic examples of these types of predisposition include the genes for hyperlipidemia and Apo A-1 mutants. Whereas only 1-2% of the population have the hyperlipidemia gene, these persons account for up to 25% of the population who have heart attacks before age 60. See P. Baird, "Opportunity and Danger: Medical, Ethical and Social Implications of Early DNA Screening for Identification of Genetic Risk of Common Adult Onset Disorders", in B. M. Knoppers & C.L. Laberge, eds., *Genetic Screening: From Newborns to DNA Typing* (Amsterdam: Elsevier, 1990) 279. Also consider the following example: 32% of people who had severe coronary artery disease before age 60 have an Apolipoprotein A-1 mutation. Again, an insurance company would witness substantial cost savings if it could eliminate this health problem from the insurance pool, see U.S. Congress, Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace*, OTA-BA-455 (Washington, DC: U.S. Government Printing Office, 1990), at 93.

95 *Zurich*, *supra*, note 69, at 378.

> of the respondent's argument relying on the absence of other classification schemes. If this were so, complacency and a history of discrimination would be rewarded at the cost of progress and the recognition of higher societal norms of behaviour.

In the context of human genetics, for those who fall with the first group, that is, single-gene disorders, the evidence is clear. Huntington disease is virtually certain to develop in those who have the gene. The genetic markers for the disease and the statistical evidence of onset are certain. As in present practice, the few diseases that fall under this category may well be considered as "reasonable and *bona fide* grounds" of discrimination. However, the second group of genetic disorders, discussed above, requires additional genetic epidemiological studies, in order to chart accurately the incidence, gravity of expression, and temporal onset induced by the genetic condition in question. While the Supreme Court of Canada accepted the standards of the industry, the industry itself is increasingly under public scrutiny.[96]

One further point to be considered is the danger of leaping to the conclusion that insurance companies are likely to misinterpret the meaning of test results and begin to discriminate against individuals on the weakest of genetic evidence. It must be recognized that it would be unreasonable to think that insurance companies would implement genetic testing requirements in the absence of solid scientific evidence as to their validity. Notwithstanding the history of sickle-cell blood testing in the United States, the fear that the industry will discriminate amongst clients on the basis of an unestablished genetic test result is unrealistic. No insurance company can hope to survive if it is introducing meaningless distinctions into its criteria for categorizing clients. As one author has stated:[97]

> The balancing act between narrowing the population eligible for insurance and containing insurer's financial risks is the very meat of underwriting and has always been a problem. Insurers have little interest in getting such refined predictors of disability and mortality that they can sell insurance to only a small fraction of the general population. This defeats the purpose of insurance, dramatically increases the transaction costs of marketing products and assessing new clients, and narrows the potential market.

Even where such scientifically valid and reliable genetic information is collected, there are particular confidentiality concerns.

(c) Confidentiality and Privacy

As insurers increasingly have access to genetic information, they will be the holders of extremely sensitive information. Often by virtue of family histories, they will also have information on other immediate family members and relatives, and this for future generations

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96 Knoppers, *supra,* note 11. See also, J. Miller, "Genetic Testing and Insurance Classification: National Action Can Prevent Discrimination Based on the 'Luck of the Genetic Draw'" (1989) 93 Dickinson L. R. 729, at 757.

97 R.M. Cook-Deegan, "Public Policy Implications of the Human Genome Project" in *Genetics, Ethics and Human Values* (Geneva: CIOMS, 1991) 56, at 64.

since genetics is not only familial but intergenerational. While the privacy and confidentiality of medical records containing genetic information is the subject of a separate chapter,[98] it is necessary to examine briefly what may be the specific obligations of the insurer who is privy to this information.

It has been noted that the majority of medical records in the hands of third parties are those in the possession of insurers.[99] Further, insurers' requests for information have expanded to require an applicant's entire medical record.[100] Applicants are often requested to sign blanket consent forms that allow insurers to examine their entire medical history and such records may be further disclosed to databases such as the MIB.[101]

Although insurers have traditionally been extremely circumspect and cautious in their treatment of medical information,[102] a recent study responding to consumer fears and expectations found that "even though genetic testing represents yet unrefined technology, the life and health insurance business would be well advised to think ahead in terms of the confidentiality expectations of its insurance-buying public and of the increased concerns that thus far have been raised by the media, consumer groups and others".[103] More importantly, this study came to the conclusion that genetic information, like AIDS-related information, warranted a program in which both types of information would be treated with "a special degree of care".[104] It suggested four specific confidentiality principles.

First, in contrast, to the usual "carte blanche" clause giving permission to the insurer to share information with the MIB, for the purposes of risk assessment or loss analysis, the study suggested—unlike the recent *Frenette* decision of the Supreme Court of Canada[105]—

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98 See *infra*, ch. 9.

99 Brom, *supra*, note 48, at 142, citing L. Andrews, Medical Genetics: A Legal Frontier 1 (1987), at 205.

100 *Ibid.* Additionally note that physicians commonly release an entire medical record to an insurer, thereby disclosing genetic information, even though the entire record was not specifically requested. See ASGH Ad Hoc Committee, *supra*, note 9 at 330 and Nys, *supra*, note 47 at 3 who notes that "there ought to be relevance between the information requested and its purpose as well as proportionality between the obligation to disclose information on one's health risks and preconditions on the one hand and the infringement of the privacy this may represent on the other".

101 See *supra,* note 52, and accompanying text.

102 American Council of Life Insurance, *Genetic Test Information and Insurance: Confidentiality Concerns and Recommendations* (Report of the ACLI Subcommittee on Privacy Legislation to the Task Force on Genetic Testing), (Washington, DC: 1991) at 10; Contrast this with "How Drug Companies Get Medical Records of Individual Patients" *The Wall Street Journal* (February 27, 1992) A1.

103 *Ibid.*, at 2.

104 *Ibid.* As we enter an era where genetic testing will undoubtedly become ever important in medicine, it is unlikely that genetic tests can be segregated from medical records. As genetic tests become not only cheaper but standardized, genetic data will be part of virtually all medical records.

105 *Frenette* v. *Metropolitain Life Ins. Co.,* [1992] 1 S.C.R. 647. While in this case, the deceased had a life insurance contract with an express waiver of confidentiality, the Supreme Court held that in any event an

that any and all redisclosures be subject to specific authorizations.[106] Second, even where there is a clear renunciation of confidentiality, redisclosures should be limited to only what is reasonably necessary for the recipient to perform its function. Third, internal operating procedures and policies should be put in place restricting authorized access. Finally, "[i]nsurers should publicize their confidentiality policies and the restrictions they impose on the redisclosure of genetic test information".[107] Nevertheless, no mention was made of restricting in any way the "carte blanche" access to the whole medical record in the first instance.

The adoption of these recommendations would go a long way in allaying public fears and individual reticence with regard to the current practices of the insurance industry. Such a self-regulatory approach may well stem the tide towards the more radical European approaches yet still call for general reforms within the industry.

4. CONCLUSION AND RECOMMENDATIONS FOR REFORM

The advent of genetic testing will affect significantly the insurability of certain individuals. For some, it will have a negative affect, by identifying them as individuals who have or are certain to develop genetic disease, as carriers of a genetic disease, or as genetically predisposed to a genetic disease. For others it may be positive, by distinguishing them as non-carriers or non-affected when they come from an affected family, thus providing access to lower premiums.[108] It is therefore likely that all individuals cognizant of their own genetic status will be required to disclose this information to insurance companies, to ensure equality of information between the insurer and the insured.[109]

Persons who have or who are certain to develop a genetic disease may become "uninsurable" or be forced to pay very high premiums as genetic technology advances. Being refused insurance will seriously alter the economic circumstances of these individuals and their families. Personal knowledge of genetic risk may then become more economically and socially "risky" than the condition itself. Moreover, a deliberate trend away from knowledge through personal diagnosis or even the refusal to be tested at the request of a family member seeking to establish their own status could have disastrous results for familial and conjugal relationships as well as for the physician-patient relationship, to say nothing of the prevention

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insurance company should have an unrestricted right of access where the contract was the subject of judicial proceedings.

106 American Council of Life Insurance, *supra,* note 99, at 4.

107 *Ibid.*

108 One author has noted that employing genetic testing may put the insurance industry on a collision course with itself in that applicants with negative test results may have heightened expectations of health and longevity and as a result may have little incentive to purchase large amounts of coverage or any insurance at all. The result may be that genetic testing by insurers may prevent significant numbers of applicants, both healthy and unhealthy, from obtaining insurance at affordable rates. See Brom, *supra*, note 48 at 135-6.

109 de Wit, *supra,* note 93, at 56.

and treatment of genetic diseases. Is this a matter of sufficient political and moral consequence that judges or legislators should take action against it? As stated by one author, insurability "is not a trait but a concept of membership. It expresses the criteria used by a group to decide whom to include and exclude from its redistributive system. Treated as a scientific test about individuals...[i]t disguises fundamentally political decisions about membership in a community of mutual responsibility."[110] This issue can be answered only to the extent that the guarantee of a minimum level of insurance in these circumstances can be justified by a collective agreement to accept the diversity, and concomitant expense, of our genetic heritage out of respect for the principles of solidarity and equity.[111]

The very functioning of insurance depends on risk factors, risk classification, pooling, and differentiation. Thus, while legitimate discrimination may be warranted, unjustified, arbitrary discrimination, which has little regard for the rights of individuals, is not. The greatest difficulty lies in achieving a balance between the insurer's right to test and the insured's right to privacy. Indeed, a "[r]estatement that individuals have freedom of choice in personal health matters, the right to work and to conduct this pursuit in a safe place, the right to privacy, and the right to certain entitlements, including health care and the ability to insure the economic safety of the family, needs to accompany the 'genetic revolution'".[112] In light of the foregoing, the Commission recommends that there should be a five-year moratorium on requests for genetic testing, questions about genetic conditions, and requests for access to genetic information in medical records, to provide an opportunity for all concerned to develop sound policies. Although comparable to a total prohibition, this could forestall a more radical legislative response based on public perceptions of the industry profiteering from "congenital bad luck". The need, at this time, to consider both the risk classification requirements of the insurance industry and the probabilistic nature of genetic conditions, currently support a ban on genetic testing and the use of test results by health and life insurers. The Commission further recommends that, during this moratorium, the insurance industry should establish a requirement of actuarial fairness so as to develop standards of accuracy, validity, and predictive value for the use of genetic tests on insurance. In order to incorporate actuarially sound genetic knowledge in underwriting practices legitimately, further genetic epidemiological studies should be conducted so that premiums charged reflect true risk. General recommendations regarding general selection and risk classification criteria should be approved by the Insurance Commissioner, and publicized so as to avoid adverse selection. In addition, the Commission recommends that, during this moratorium, the insurance industry should consider creating risk pools with community rating based simply on currently obtained family histories, without requiring individual information or testing for those families or populations identified as at risk for having single gene disorders. This would

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110 D. A. Stone, "AIDS and the Moral Economy of Insurance" (1990) 1 American Prospect 62-73 at 68. See also "Bad Luck Insurance" (1990) 347 Nature (September 20) 214: "The remedy, not the answer, is that congenital bad luck is a communal responsibility".

111 Knoppers, *supra,* note 29, at 50 .

112 P. Billings, "The Context of Genetic Screening" (1991) 64 Yale J. of Biol. Med. 47 at 47. See also H. Guay, B.M. Knoppers & I. Panisset, "La génétique dans les domaines de l'assurance et de l'emploi (en droit civil québecois) (1992) 52 R. du B. 185.

avoid forcing persons to know their status in order to be insured. Indeed, there might very well be a right not to know, particularly where there is no treatment available. Patient associations for these diseases should be involved actively in the process of such proposals, since this principle of risk-spreading would have to be acceptable. The insurance industry cannot force such solidarity; it has to come from those who are potentially affected. The compromise that is made would have to disperse the expense of certain genetic conditions or predispositions among those who might be most willing to pay for it—other family members and other persons in at-risk populations for the disease who may or may not wish "to know" due to the social and personal stigmatization currently accompanying genetic disease.

Finally, as an alternative, or in addition to the above proposals, the Commission recommends that there should be a standard "no questions asked" policy, in which the amount of insurance requested is proportionate to the social and financial circumstances of the applicant, or at the very least, for a minimal amount of life insurance for all. Above this level, insurers should be permitted to demand access to genetic information. This would demonstrate not only an understanding on the part of the industry of the inherent nature of genetic diseases, and of the economic necessity in modern industrialized countries of a minimum of life insurance in itself and as a means of access to other economic products, but also provide the basic security necessary for dependants. Such an approach is consistent with Canadian values.

CHAPTER 7

GENETIC TESTING IN EMPLOYMENT

1. INTRODUCTION

Of all its possible applications, genetic testing in the context of employment has received the most "official" attention, after that given to insurance. While subject to human rights legislation and unfair labour practices legislation, an employer is otherwise free to select or reject any job applicant.[1] Employers often use pre-employment medical assessments, of which genetic tests can be a subset, in their assessments of an applicant's aptitude for a particular position.[2] In Ontario, employers are also required by law to undertake medical tests for certain job applicants and employees.[3] Given the potent power of genetic testing technology to reveal hitherto unforeseen conditions, particularly in the area of susceptibility to occupational disease, the time is ripe for an examination of the law in this area.

An employer might use two distinct forms of new genetic technology, each of which pursues different objectives and raises different questions. First, an employer might make use of "genetic screening" in the pre-employment (application) stage or during the course of employment. Screening is a one-time test that can identify genetic susceptibility or predisposition to a disorder in an asymptomatic population. At least two dozen genes

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1 I. Christie, G. England & B. Cotter, *Employment Law in Canada, 2d ed.* (Toronto: Butterworths, 1993) at 61.

2 See for example, Ontario, Commission of Inquiry into the Confidentiality of Health Information (Hon. Mr. Justice H. Krever, Commissioner), *Report of the Commission of Inquiry into the Confidentiality of Health Information,* vol. 3 (Toronto: Queen's Printer, 1980) at 183. (Hereinafter *Krever Commission Report*)

3 *Occupational Health and Safety Act*, R.S.O. 1990, c. O.1, s. 26(1)(j), s. 70(2)18, R.R.O. 1990, Reg. 833 Control of Exposure to Biological or Chemical Agents, s. 8 (testing is for employees, not applicants); Designated Substance Regulations, R.R.O. 1990, Reg. 835 through 846, ss. 7(1),(2)(d), 13, in the Code for Medical Surveillance portion of each regulation - medical examinations including a medical history, a physical examination and prescribed clinical tests are required before employment or placement of workers and at periodic intervals in jobs involving exposure to a designated substance. Mandatory medical exams can be advantageous (justified) on three grounds: 1. to check the efficacy and efficiency of controls; 2. to detect adverse effects on worker health at an early stage; and 3.to educate workers about health effects of exposure to hazardous substances and the precautions to be taken - Advisory Council on Occupational Health and Occupational Safety (Ontario), "Advisory Memorandum 87-V, to the Minister of Labour, December 29, 1987, concerning mandatory post-exposure medical examinations", in *10th Annual Report, April 1,1987 to March 31, 1988* at 130-31. Further, *the Canada Occupational Safety and Health Regulations,* SOR/86-304, s. 10.20(2)b), states that an employer must not permit an employee to work with a dangerous substance "until a medical practitioner, acceptable to the employee has examined the latter and declared him fit for the work with the dangerous substance". None of the above statutes, however, explicitly mention genetic screening.

indicating particular sensitivity to certain chemicals have been identified, and susceptible individuals, if exposed to a particular environment, will become ill.[4] In contrast, genetic predispositions only rarely point to conditions with a certainty of onset.[5] The vast majority identify only a *possibility* of developing a disorder.[6]

Second, employers might use "genetic monitoring",[7] which occurs periodically and studies non-inherited genetic damage induced from exposure to workplace hazards.[8] Scientific studies have established and documented a clear correlation between exposure to selected chemicals or ionizing radiation and damage to genetic material. Such damage can result in cancer or other illnesses and may therefore be a useful indicator of health risks. Monitoring is undertaken with the objective of detecting hazards at an early stage. It is important to note that this technique does not rely on the crucial information-coding capacity of DNA and, to this extent, is similar to any other type of biochemical (biological) testing for exposure to deleterious substances.

The use of both pre-employment screening and genetic monitoring by employers is not yet extensive. A 1989 survey by the United States Office of Technology Assessment reported that only thirty three of the 500 largest United States corporations reported using any type of genetic testing, either currently or in the past.[9] This number represented little or no real increase over a similar survey done in 1982.[10] While business has found only limited application for genetic testing at this time, there is reason to believe that it will increase as it becomes more affordable and as the number of tests for the more common multifactorial

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4 U.S. Congress, Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace*, OTA-BA-455 (Washington, DC: Government Printing Office, 1990), at 13. (hereinafter *1990 OTA Report*) This list was updated to 1984.

5 For example, Huntington's Disease; see Science Council of Canada, *Genetics in Canadian Health Care* (Ottawa: Supply & Services Canada, 1991) at 20. As concerns cystic fibrosis, since the initial finding of the F508 mutation, which is responsible for 70% of cases, over 500 other mutations have been discovered. Already, the Science Council of Canada has called for guidelines, and where necessary, legal instruments to protect the rights of individuals. It has suggested that other criteria must be satisfied before genetic testing is introduced into the workplace. The Science Council has set out prerequisite criteria that employment-related tests must be scientifically valid, related to the job, and not a substitute for cleaning up the work environment.

6 *Ibid.*, at 23.

7 For a detailed explanation of "genetic monitoring", see *1990 OTA Report, supra,* note 4, at ch. 4.

8 The two types of genetic monitoring are cytogenetic and non-cytogenetic. Cytogenetic monitoring looks for damage to the structure of the chromosome, such as chromosomal aberrations and sister chromatid exchanges. Non-cytogenetic testing looks for damage to the molecular structure of the DNA.

9 *1990 OTA Report, supra*, note 4, at 177. Note that 27 of these corporations employed over 10,000 workers.

10 *Ibid.*, at 178.

diseases increases.[11] There is therefore potential for great development and concomitant use of these techniques in the near future.

Irrespective of the present limited application of workplace genetic testing in North America, rapid advances in genetic research have prompted other jurisdictions to examine the question and adopt prospective policy, and even legislative, positions. These positions will help clarify the issues for our study of the Canadian context. In 1989, the European Parliament adopted the following resolutions: Selection on the basis of genetic predisposition must never be an alternative to cleaning up the workplace; a statutory ban should be placed on the selection or monitoring of workers on the basis of genetic criteria; pre-employment examinations must be limited to specific occupational requirements and be carried out by a physician of the potential employee's choice; results must be given to the individual and passed on only by her or him; employees should have the right to refuse genetic testing without consequences and finally, there should be no storage of genetic data on workers.[12] The Committee of Ministers of the Council of Europe also recommended that "the continued exercise of certain activities, especially employment, should not be made dependent on the undergoing of genetic tests or screening".[13]

Similarly, a German commission argued that collection or use of genetic information should be prohibited. Any exception would require a statutory legal base and even an employee's consent to testing, because the factual situation of constraint would not permit employers to circumvent the rule. Pre-employment exams would be legally permissible only when necessary for the protection of other employees or third parties. With regard to genetic predispositions, employers must bear the risk, not the employees. Furthermore, prohibition of gene analysis in connection with employment was seen as necessary to ensure the informational self-determination of the employee. The Commission also stated that employers should be prohibited by law from having access to outside genetic information from tests done elsewhere or as part of a research project.[14]

Likewise, the Health Council of the Netherlands rejected the use of tests for genetic predisposition as part of job-selection procedures, either to check for genetically determined sensitivity to toxic substances in the place of work or the possibility of developing hereditary disorders later in life. If sufficiently reliable tests were to become available in the future, the

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11 N.A. Holtzman, *Proceed with Caution - Predicting Genetic Risks in the Recombinant DNA Era* (Baltimore: Johns Hopkins University Press, 1989) at 200-201. It is important to note that only the proliferation of screening tests for common multifactorial disorders, such as heart disease, cancers and major depression, will expand the context of genetic screening from industrial settings to workplaces in all economic sectors.

12 European Parliament, *Ethical and Legal Problems of Genetic Engineering and Human Artificial Insemination* (Luxembourg: Office for Official Publications of the European Communities, 1990) at 13.

13 Council of Europe, Principle 6 of Recommendation No. R(92)3 on Genetic Testing and Screening for Health Care Purposes in *Texts of the Council of Europe on Bioethical Matters* (Strasbourg: Directorate of Legal Affairs, 1993).

14 Resolution of the Conference of the Data Protection Commissioners of the Federal Republic of Germany, October 26-27, 1989.

Council argued that their use should be considered only in special situations, where the health interests of the person concerned, or of those of a third party could be demonstrated to be at stake. Medical examinations at the time of joining collective pension and disability schemes were held to be unnecessary and unproductive.[15]

Both The Nuffield Council on Bioethics[16] and the House of Commons Select Committee on Science and Technology[17] in the United Kingdom are of the opinion that no current genetic tests are sufficiently robust enough to warrant insistent disclosure to employers. They acknowledge, however, that genetic testing may, in time, be sensitive enough to determine persons at risk to the environmental effects of particular substances. Accordingly, the Nuffield Council has recommended, and the Science and Technology Committee has affirmed, that genetic screening for employment purposes should be contemplated only where: there is strong evidence of a clear connection between the working environment and the development of the condition for which screening is conducted; the condition in question is one that seriously endangers the health of the employee; and the condition is one for which the dangers cannot be eliminated or significantly reduced by reasonable measures taken by the employer to modify or respond to the environmental risks.[18] The Science and Technology Committee further noted that, while the employee should have the right to decide whether to participate in such screening, the employer should have defences available should an action be taken against the employer by an employee who had exercised his right to refuse screening and subsequently developed a work related illness to which he was particularly susceptible.[19]

In the United States, employers are often the medical and disability insurers of their employees and thus have a great interest in reducing their health-care expenses. At the federal level, the *Americans with Disabilities Act of 1990 (ADA)* protects disabled persons against discrimination when the individual can, with or without reasonable accommodation, perform the essential functions of the job.[20] People with manifest symptoms of severe genetic disease are covered by the Act. However, the regulations do not state expressly that individuals predisposed to genetic disease or unaffected carriers of genetic disorders are covered when

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15 Health Council of the Netherlands, *Heredity: Science and Society* (The Hague, 1989) at 141-154.

16 Nuffield Council on Bioethics, *Genetic Screening: Ethical Issues* (London: Nuffield Council on Bioethics, December 1993) para. 10.12.

17 House of Commons Select Committee on Science and Technology, *Human Genetics: The Science and its Consequences,* Third Report of the Science and Technology Committee 1994-95, July 6 1995, at para 232.

18 Nuffield, *supra*, note 16 at para. 10.13 and House of Commons Select Committee on Science and Technology, *ibid.*, at para 233.

19 House of Commons Select Committee on Science and Technology, *ibid.*

20 Cong. Rec. S10954-01, Title I - Employment s. 101(7). Note that the ADA simply defines an individual with a disability as an individual who has a mental or physical impairment that substantially limits one or more of the individual's major life activities (e.g. walking, seeing, hearing, working), has a record of such an impairment, or is regarded as having such an impairment.

the basis for their exclusion is, respectively, the fear that the individual might become disabled at a later date or might parent an affected child.[21]

When this legislation was initially introduced, the Equal Employment Opportunity Commission (EEOC), responsible for implementing the law, was of the opinion that asymptomatic but genetically susceptible individuals were not covered by the ADA. As a result, individuals with late-onset disorders, carriers of recessive disorders, and carriers of X-linked disorders could be legally denied employment.[22] However, in March 1995, the EEOC reversed its position and held that genetic susceptibility to disease is a protected disability within the meaning of the ADA.[23] In order to qualify for protection under the terms of the ADA, individuals must show that they have a genetic predisposition, that they were "regarded as disabled" by an employer, and that they were discriminated against because of that perception.[24] Although the EEOC's finding is ostensibly intended to render genetic discrimination illegal across the United States, it is not binding on the courts. Further, it has been met with some criticism as it relies on the tortuous logic of perceived disability rather than fundamental civil rights regarding all persons as equal regardless of their genes.[25] Moreover, it does not prohibit employers from requiring individuals to release their entire medical records or undergo a comprehensive medical examination (including genetic testing) as a condition of employment. Although ADA regulations protect the job applicant from irrelevant medical testing, once a conditional offer of employment has been made, post-offer testing for "non-job related criteria" is not proscribed. While it may be unlawful to exclude an individual for a health reason that is unrelated to the individual's ability to perform the job, it may be difficult to prove that the employer acted illegally.[26] The NIH-DOE Joint Working Group on Ethical, Legal and Social Issues has recommended that post-offer employment entrance examinations be limited to assessing job-related physical and mental conditions only.[27]

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21 See M.A. Rothstein, "Genetic Discrimination in Employment and the Americans With Disabilities Act" 1992 29:1 Houston L. J. 23.

22 Holtzman & Rothstein, "Invited Editorial: Eugenics and Genetic Discrimination" (1992) 50 Am J. Hum. Genet. 457 at 458, citing E. Juengst, "Priorities in Professional Ethics and Social Policy for Human Genetics" (1991) 266 J.A.M.A. 1835.

23 Barbara J. Culliton, "Genes and Discrimination" (1995) 1 (5) Nature Medicine 385.

24 M. A, Rothstein and B.M. Knoppers, "Legal Aspects of Genetics, Work, and Insurance in North America and Europe" (1996) 3:2 J. Health Law (in press). See also The Washington Post, "Gene Discrimination Barred in Workplace: EEOC Says Jobs Can't Be Denied Based on Predisposition to Disease" April 7 1995, P.A3.

25 See "US Bans Gene Prejudice at Work" (April 22 1995) New Scientist 4.

26 Rothstein and Knoppers, *supra*, note 24.

27 Joint Working Group on Ethical, Legal and Social Issues in Human Genome Research, "Statement of Recommendations Concerning Genetic Discrimination and ADA Implementation" (1991) 3:3 Human Genome News 12 at 13. (Hereinafter ELSI).

The intent of the EEOC's restatement reflects the opinion of many commentators, although most prior proposals were not based on "regarded disability". Gostin suggested that the ADA be extended to "those having a genetic or other medically identified predisposition toward such an impairment".[28] Another author proposed a National Genetic Anti-Discrimination Act,[29] the aim of which was to overcome the ADA's requirement that the impairment must "limit a major life activity" and prohibit genetic discrimination. The Act would establish a joint commission with powers to promulgate rules and regulations, set forth criteria of what constitutes genetic discrimination, specify the burden of proving discrimination and provide for compensatory and punitive damages. It would be unlawful, under this model act, for an employer to discriminate against a carrier of a genetic trait, or person with a genetic defect, mutated gene or disease-susceptible gene, unless the employer demonstrated that the gene or trait directly impaired a person's ability to perform the job.[30]

The *Human Genome Privacy Act* [31]was another attempt to legislate in this area. This law would have extended the right to privacy to cover genetic information, prevented genetic information about an individual from being made available to third parties without the person's consent, and permitted the correction of records. While the Act proposed stiff penalties for violations, it would not have protected most individuals, due to the pressure experienced by job applicants to consent to testing.[32] The Act was defeated in the United States House of Representatives and was replaced in 1994 by the proposed *Health Information Fair Practices Act.*[33] This latter Act, which is much broader in scope, protects genetic data under the umbrella category of health information that "relates to the past, present, or future physical or mental health of an individual".[34]

In 1991, the Governor of California vetoed a proposition to include genetic characteristics as a forbidden ground of discrimination under civil rights legislation although both Houses had passed the bill. The proposition would have prevented employers from using genetic testing for pre-employment purposes. The Governor justified his veto: "I am concerned that we are providing a remedy for a problem whose nature and magnitude are not yet sufficiently defined".[35] Indeed, while environmental workplace toxicity has long been the

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28 L. Gostin,. "Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers" (1991) 27 *American Journal of Law & Medicine* 109, at 143.

29 C.B. Gurd, "Whether a Genetic Defect is a Disability Under the Americans With Disabilities Act: Preventing Genetic Discrimination by Employers" (1992) 1 Annals of Health Law 107 at 115.

30 *Ibid.,* at 117.

31 H.R. 5612, 101st Cong., 2d Sess. (1990).

32 T. Beardsley "Fatal Flaw: Who Will Have the Right to Examine Your Genes?" (1991) 256:6 Scientific American at 14.

33 H.R. 4077, March 14, 1994.

34 *Ibid.*, s. 3(3).

35 "Privacy Bill Vetoed" (1991) 353 Nature 687.

subject of protective legislation, the use of predictive diagnosis through genetic testing will change medical practice and language in the workplace from symptomatic diagnosis to risk diagnosis, which is a concept that is not commonly understood.[36]

Finally, the United States Office of Technology Assessment has laid out basic legislative options. Alternatives to be considered by the federal government with regard to regulating genetic screening and monitoring include: (1) amending a section of the *Occupational Health and Safety Act* to specify whether genetic monitoring and screening are to be included in its standards for medical examinations; (2) amending the Act to guarantee the confidentiality of genetic monitoring and screening results; (3) requiring full disclosure of the nature and purpose of all medical procedures performed on employees and job applicants; (4) allowing genetic changes to be included in regulatory definitions of occupational illness; (5) amending federal law to prohibit discrimination in hiring against otherwise qualified applicants because their genetic screening results reveal a predisposition to future disease; and (6) directing the National Labour Relations Board to make pre-employment genetic screening a mandatory subject of collective bargaining.[37] For its part, the Institute of Medicine advocates the adoption of a law that would forbid employers to collect genetic information on prospective or current employees, unless it were clearly job-related.[38]

The Privacy Commissioner of Canada recommends that employers should be prohibited generally from collecting personal genetic information about job applicants or employees through mandatory or voluntary genetic screening.[39] All Canadian Human Rights legislation, as discussed below, prohibit discrimination in the employment context. The wording of the Ontario *Human Rights Code*, for example, which refers to equal treatment with respect to employment without discrimination because of handicap, is very broad and thus suggests that it would protect pre-employment practices, practices during employment, and dismissal.[40] Further, it is likely that genetically susceptible but asymptomatic individuals will be covered by the expansive definitions of "handicap" and "perceived disability".[41] An employer's attempt to use genetic susceptibility as a *bona fides* occupational requirement likely will fail

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36 It is interesting to note that, in Denmark, a proposed ban of genetic testing for the purposes of employment, pensions and insurance was passed despite vocal opposition from trade unions who saw some utility in the genetic monitoring of workers. See Hodgson, J. "Denmark Bans Use of Testing Info" (1991) 9 Biotechnology 508.

37 *1990 OTA Report supra,* note 4, at 24-28.

38 Committee on Assessing Genetic Risks, Institute of Medicine, (L.B. Andrews et al., eds.) *Assessing Genetic Risks: Implications for Health and Social Policy* (Washington, DC: National Academy Press, 1994) at 24.

39 The Privacy Commissioner of Canada, *Genetic Testing and Privacy* (Ottawa, Ontario: Minister of Supply and Services Canada; 1992)

40 Nancy Park and Bernard Dickens, "Legal and Ethical Issues in Genetic Prediction and Genetic Counselling for Breast, Ovarian and Colon Cancer Susceptibility," in (1995) Critical Choices : Ethical, Legal and Social Behavioural Implications of Hereditable Breast, Ovarian and Colon Cancer (Background Papers, International Research and Policy Symposium, Toronto, April, 1995) 61 at 85.

41 *Ibid.*

where genetic susceptibility is not related to the performance of a specific job. It is still unclear, however, whether individuals with genetic predisposition to disease will be covered by the *Code* given that the perceived disability takes place in the future.

The differing perspectives on the possible role of genetic testing within industry are discussed below. Any implementation of genetic testing in the employment sector, while still "futuristic", requires analysis in order for the policy issues to be understood and possibly for "preventive" purposes. In law, the issues can be divided into several categories: human rights and discrimination on the basis of genetic predisposition; legal defenses to such discrimination; and confidentiality of an employee's genetic information. These are the issues, discussed in turn below, in which the delicate balance between the rights of employers and those of workers needs to be forged by judges and legislators.

2. CURRENT PERSPECTIVES

At the outset, it should be stated that, with the exception of single gene disorders, the scientific validity of pre-employment or workplace genetic testing must still be considered as questionable.[42] Further, given its present expense and availability, genetic testing in the workplace is still an issue primarily for the future. It is doubtful that the current tests can predict predisposition to harm from workplace exposures with sufficient accuracy to justify the testing or removal of susceptible workers. The United States Office of Technology Assessment has stated that the relationship between a mutation and a health effect is not well understood.[43] Even with new technology, it is likely that a range of susceptibility levels will be found instead of a situation in which one group of persons is highly susceptible while everyone else is resistant.[44] The implementation of genetic monitoring and pre-employment screening is therefore problematic, given the lack of predictiveness as well as the difficulties in eliminating biases and obtaining suitable control groups.[45]

This scientific uncertainty is the source of heated debate between employers and workers. Views on the role of genetic testing in employment generally depend on how one interprets the balance of rights between employer and employee, and the school of labour relations to which one subscribes. Opinions about the use of a particular genetic test are influenced by values concerning acceptable risks, racial characteristics, and gender of the workforce as well as by expectations about control of testing programs and the genetic

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42 *1990 OTA Report, supra,* note 4, at 9. Also, L. Gostin, *supra,* note 28, at 114 the author states that the sensitivity of the tests is limited by the characteristics of the target population. Further, due to the disease variability, it is difficult to predict the nature, severity and course of disease based on the genetic marker. Finally, multifactorial diseases depend upon complex interactions among genetic and environmental factors. There is therefore much scientific uncertainty regarding employment genetic testing.

43 *Ibid.,* at 71.

44 Holtzman, *supra,* note 11, at 202.

45 *1990 OTA Report, supra,* note 4, at 70.

information they produce.[46] In theory, testing could benefit both the employer and worker, helping the employer place the worker in the most appropriate position while assisting the employee in minimizing his or her exposure, and thus the probability of developing a disease or disability, or from becoming symptomatic. The information could therefore be very empowering to both sides. However, such testing creates ethical and legal debates in the workplace regarding individual freedom versus social control; autonomy versus paternalism; equal opportunity versus health protection; genetic discrimination versus free enterprise and finally, privacy versus interference.[47] In short, who is to bear the risk?

Moreover, the potential uses of genetic information raise at least three philosophical problems. The first problem is that of reductionism, that is, the tendency to reduce a complex, multivariate problem to one involving a single factor. Second, determinism is the misconception that genes, instead of being mere predictors, determine one's destiny.[48] Third, with such testing, responsibility for workplace risks and related choices may well shift back to the employee. According to one author, there has been an ideological shift in the prevailing theory of risk, from one involving hazardous working conditions, which places responsibility on the employer, to one of individual or genetic susceptibility of the worker, as the primary cause of occupational disease.[49]

New technological developments have resulted in a shift in focus from a systemic view of the relationship between economics and disability to the "high-risk worker" who is now, and will increasingly become, more readily discernible. As a result, general large scale issues will give way to the implementation of disease causation, which may be used as justification for denying individuals employment. Moreover, the attribution of illness to inborn characteristics and use of a genetic framework has taken interest away from evidence of acknowledged social and environmental influences on disease, and thus conveniently shifted responsibility away from the employer.[50] The controversy regarding workplace genetic

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46 E. Draper, "Genetic Testing in the Workplace - Competing Paradigms of Technological Advance" in D. Nelkin, ed., *Controversy: Politics of Technical Decisions,* 3d ed., (Newbury Park, CA: Sage Publications, 1992) 147 at 154.

47 H. Guay & B.M. Knoppers, "Genetic Screening and Genetic Information in the Workplace" (Address to the Conference of The American Society of Human Genetics, October 1986) [unpublished].

48 B.M. Knoppers, *Human Dignity and Genetic Heritage* (Ottawa: Law Reform Commission of Canada, 1991) at 43-46; M.A. Rothstein, "Discrimination Based on Genetic Information" (1992) 33 Jurimetrics Journal 13 at 14.

49 Draper, *supra*, note 46, at 147.

50 A California Court recently ordered a mentally handicapped child to undergo a DNA test to determine if he was permanently damaged as a result of his mother's exposure to solvents while assembling silicon wafers at KTI Chemicals Inc. The Company denied that the chemical in question could cause irreversible birth defects and argued that the child suffers from Fragile X Syndrome, a common cause of mental retardation, particularly in males. Geneticists argue that testing for Fragile X will not prove that the child's retardation is genetic. Further, if tests show that the child has an increased number of CGG repeats, a dispute is likely to arise over the extent to which the chemicals in question may have contributed to his condition. S. Lehrman, "Court Orders DNA Test Over Chemical Claims" (1994) 369 Nature 597.

testing must therefore be placed in a socio-political framework that takes into account factors such as safety, hierarchical structures,[51] as well as legal and economic forces. Considering this ideological context, it is hardly surprising that both the employer and the employee have legitimate reasons either to accept or reject the various forms of genetic testing.

(a) EMPLOYERS

As testing becomes more cost efficient and more readily available, employers might oppose genetic monitoring on the basis of the ambiguity of the clinical meaning of test results. Positive findings, although inconclusive, could cause political pressure to reduce workplace exposure, or strengthen government testing regulations. Furthermore, employees could become alarmed unnecessarily about their health and exposure to chemicals.[52]

Management generally favours genetic screening. Employers believe that science and technology generally promote human welfare, and think that labour unions and other groups oppose genetic screening because of ignorance, lack of scientific education, or fear of technology, and a basic misunderstanding of the benevolent intentions behind medical surveillance procedures. The approach of management would be to find individual, not industrial causes of problems. They believe that health hazards have been overestimated and over-regulated, and consider the workplace safe for "normal" workers.

Employers, of course, have the right to select the most productive applicants, within the twin constraints of human rights and unfair labour practices legislation.[53] It is well known that a healthy and reliable workforce is key to competitiveness.[54] A company would likely be more competitive if it could avoid hiring employees with genetic predisposition to a disorder. Amongst economic incentives are the reduction of lost work-time and worker's compensation claims. For example, although only one to two percent of the population carries the hyperlipidemia gene, those affected account for up to twenty-five percent of the population who have heart attacks before age sixty.[55] If a firm had to choose between hiring one candidate with the gene and one without, it would make financial sense to choose the latter. In other words, if a firm could eliminate every person with the hyperlipidemia gene from its

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51 Hierarchical structures refers to the intrinsically unequal power base between employers and employees. An employer can request the employee to consent to testing or access to medical records but the employee (if he or she wants the position) is not truly free to refuse such a request. It is ultimately a situation of implicit coercion.

52 Draper, *supra,* note 46, at 153.

53 Christie, England & Cotter, *supra,* note 1.

54 The cost of heart disease (of which genetics can be a significant factor) to Canadian business has been estimated at $11.6 billion yearly: Heart and Stroke Foundation of Canada, *Cardiovascular Disease in Canada* (1991) at 24.

55 P.A. Baird, "Opportunity and Danger: Medical, Ethical and Social Implications of Early DNA Screening for Identification of Genetic Risk of Common Adult Onset Disorder" in B.M. Knoppers, C.M. Laberge, eds., *Genetic Screening: From Newborns to DNA typing* (Amsterdam: Elsevier Science Publishers, 1990) 279 at 280.

workforce, it could register a twenty-five percent reduction in heart attacks suffered by its employees before the age of sixty. As the costs of pensions rise, one could similarly theorize that certain employers might wish to hire workers with a genetically high probability of dying at approximately age sixty-five or prematurely.[56]

(b) LABOUR

Workers, on the other hand, support genetic monitoring in the hope that it will draw attention to the risks of environmental chemical exposure, rather than differentiating inherently high-risk workers from those at lower risk through susceptibility testing.[57] Labour believes that the hazards, not the workers' genetic susceptibilities, should be the focus of concern. Through this logic, all workers are at risk and require protection by cleaning up the workplace.[58]

There is, however, some concern that an employer will simply relocate workers who have been identified as carriers of such genetic traits, as a less expensive alternative to implementing appropriate safety measures. Such a practice would probably be deemed discriminatory under Ontario law, unless relocation was the only way to accommodate the worker without undue hardship. Clearly, it could be in both the employer's and the employee's interests to determine genetic sensitivity before exposure to chemicals. The Science Council of Canada has suggested that genetic monitoring or pre-employment genetic testing could be beneficial if used to create a healthier work environment or to relocate high-risk individuals to safer jobs.[59] It emphasized, however, that non-employment or re-

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56 Holtzman, *supra,* note 11, at 204.

57 *Ibid.,* at 149.

58 In Canada, occupational health and safety norms lay out the obligations of employers with regard to the safety of their employees. These rules are, however, designed to address the needs of the "average" employee not those with particular health problems or requirements. While human rights legislation has provided a certain degree of relief to workers who cannot conform, by forcing employers to adapt, modify or waive safety rules, it has been argued that occupational health and safety law should be modified to cover the situations of all workers, whether they be healthy, disabled or genetically predisposed to illness. A recent policy change by the Ontario Ministry of Labour may be a first step in that direction. Procedures regarding a worker's refusal to work on the grounds of perceived danger to health or safety are applicable to all workers, including those who "because of a particular health condition, exercise a right to refuse in a situation where the 'average' worker might be able to work." A ministry inspector investigates the refusal and decides if workplace conditions are likely to endanger the worker based upon the specific health condition. The worker must provide relevant medical information to support his or her contention. Where there is a contravention of the Occupational Health and Safety Act, the inspector can issue an order compelling the employer to take action. Otherwise, the inspector can only state that workplace conditions are likely to endanger that particular worker's health and must refer the employee to either the Human Rights Commission or the Worker's Compensation Board. See Ministry of Labour, *Policy and Procedures Regarding Refusal to Work Where a Worker's Health May be Endangered,* (Toronto: MOL Policy Division, 1992) and D. Leitch "Occupational Health and Safety and Human Rights in the Workplace: Not Always a Comfortable Fit" (1993) 2 Can Lab. L J. 231.

59 *Science Council of Canada, supra,* note 5, at 77.

deployment of genetically susceptible employees or applicants should not be a substitute for improving occupational conditions and environment.[60]

Employees and job applicants, as possible subjects of genetic testing, have a diverse set of objectives and concerns. They may be concerned about maintaining their right to refuse medical treatment in the face of an employer's mandatory testing scheme.[61] On the other hand, they may want to know how their own health is at risk, and may want to make use of health services offered by their employer. It is widely recognized that counselling and follow up testing are essential to the ethical delivery of genetic testing services.[62] Whether employers are willing to provide such extended services is so far unknown. Employers may have a duty to refer workers to a geneticist or other health care professional to advise the worker of test results, particularly given the difficulties of interpreting genetic information.[63] Furthermore, once testing has been done, privacy and confidentiality of medical information become important issues.[64]

3. HUMAN RIGHTS AND GENETIC TESTING

Human rights legislation will play a substantial role in the determination of the legality of genetic testing in the workplace. Procedural aspects of genetic monitoring and screening raise interesting issues under the *Canadian Charter of Rights and Freedoms.*[65] For instance, the drawing of body fluids from a subject raises the question of the right to physical integrity, to security of the person, and the right to be secure against unreasonable search and seizure. Furthermore, if genetic screening were ever to be mandated by legislation, it would inevitably raise the question of whether singling out genetically predisposed people would conform with the principle of equality before the law. Related to the theme of equality, the question of whether an adverse employment decision made after genetic testing reveals a predisposition might constitute discrimination on the basis of handicap will be examined below in light of both the *Canadian Human Rights Act* [66] and the Ontario *Human Rights Code* .[67]

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60 *Ibid.*, at 79.

61 See: *Malette* v. *Shulman* (1990), 72 O.R. (2d) 417 (C.A.), aff'g (1987), 63 O.R. (2d) 243 (H.C.); *Fleming* v. *Reid* (1991), 4 O.R. (3d) 74 (C.A.); rev'g (1990), 73 O.R. (2d) 169 (Dist. Ct).

62 *Science Council of Canada, supra*, note 5, at 69-71.

63 L.B. Andrews & A.S. Jaeger, "Genetic Information in the Workplace" (1991) 17 Am. J. of Law & Med. 75.

64 See *infra,* ch. 9.

65 Part 1 of the *Constitution Act*, 1982, being Schedule B of the *Canada Act*, 1982 (U.K.), c. 11 (hereinafter the *Charter)*. See, also, *infra*, ch. 3.

66 R.S.C. 1985, c. H-6. (Hereinafter the *Act*).

67 R.S.O. 1990, c. H.19. (Hereinafter the *Code*).

(a) CHARTER ISSUES

Were a government to enact laws governing testing programs in the workplace, by mandating testing, or simply providing a framework within which testing would be permitted, such legislation would be subject to constitutional challenges under the provisions of the *Charter.* Similarly, testing programs could be contested in workplaces with sufficient government nexus to be considered government action under section 32.[68]

A reasonable expectation of privacy could be derived from the decision in *Hunter* v. *Southam,*[69] based on the broad and general right, under section 8 of the *Charter,* to be secure from unreasonable search and seizure. Further, in *R.* v. *Dyment ,*[70] the section 8 guarantee was found not to be restricted to protection of property, but to protect three zones of privacy: (1) territorial or spatial (property); (2) privacy of the person (from physical search and indignity); and (3) informational privacy, the assumption being that all information about a person is in a fundamental way her own, for her to choose whether to communicate or to retain for herself.

It could also be argued that mandatory testing programs requiring individuals to provide samples of bodily fluids under coercion, would constitute a deprivation of liberty and security of the person as protected in section 7 of the *Charter.*[71] Were the courts to rule that a mandatory testing program would violate either section 7 or 8, legislation mandating such testing could still be upheld under section 1. Under the test elaborated in the *Oakes*[72] case, the courts would have to determine whether genetic testing to prevent occupational disease is a matter of pressing and substantial concern in Canadian society and whether testing methods are proportional and appropriate to the legislative objective.

Finally, section 15(1) of the *Charter* provides as follows:

> 15.—(1) Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.

Under the *Charter*, individuals impacted adversely by a law mandating genetic testing could submit that such legislation was unconstitutional because it would violate their right to equality. Because of the unique wording of the section, which also prohibits discrimination

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68 See Wilson J's three part test in *McKinney* v. *University of Guelph*, [1990] 3 S.C.R. 229.

69 [1984] 2 S.C.R. 145.

70 [1988] 2 S.C.R. 417. See also *R.* v. *Dersch* (1993), 25 C.R. (4th) 88 (S.C.C.).

71 Support for such an approach would be found in *R.* v. *Morgentaler,* [1988] 1 S.C.R. 30, 44 D.L.R. (4th) 385; *Re Dion and the Queen*, [1986] R.J.Q. 2196, 30 C.C.C. (3d) 108 (Que.S.C.).

72 *R.* v. *Oakes*, [1986] 1 S.C.R. 103, at 138-39.

on non-enumerated grounds,[73] litigants could argue that they have been discriminated against on the basis of disability or an analogous ground, such as health or genetic makeup. Once again, if discrimination were to be found, a testing program could still be justified under section 1.

Discrimination against workers or job applicants on the basis of genetic screening results is the main spectre raised by the advent of workplace testing. Clearly, discrimination on the basis of a manifest genetic condition, when considered a handicap, is prohibited under all existing legislation.[74] However, certain groups of workers might still be at risk of discrimination, in particular, those who are asymptomatic but carry a gene that increases the probability that they will develop a disease—that is, those with a predisposition, although there is no certainty as to the moment of onset or severity of the disease—and unaffected carriers (heterozygotes) of genetic conditions that could be passed on to their offspring.[75] Faced with such cases, an employer could discriminate based on a perception of disability.[76] What remains to be seen, however, is whether the *Canadian Human Rights Act* and the Ontario *Human Rights Code* respond adequately to these cases.

It is important to note that two distinct types of discrimination have been recognized explicitly and prohibited by both these laws. Direct discrimination occurs where an employer adopts a practice or rule that, on its face, discriminates on a prohibited ground. On the other hand, constructive (or adverse effect) discrimination arises where an employer, for genuine business reasons, adopts a rule or standard that is neutral on its face and will apply equally to all employees, but that has a discriminatory effect upon a prohibited ground on one employee or group of employees because it imposes, due to some special characteristic of the employee or group, obligations, penalties, or restrictive conditions not imposed on other members of the workforce. The Supreme Court of Canada has distinguished these two types of discrimination in *Ontario Human Rights Commission and O'Malley* v. *Simpsons-Sears Ltd.*[77] The distinction is an important one as provisions and remedies regarding the two forms are not always the same.[78]

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73 *Andrews* v. *Law Society of British Columbia*, [1989] S.C.R. 143.

74 M.R. Natowicz, J.K. Alper & J.S. Alper, "Genetic Discrimination and the Law" (1992) 50 Am. J. Hum. Genet. 465

75 *Ibid.*, at 466.

76 A further problem is that workplace decisions are often based solely on a diagnostic label, without regard to the severity of the condition for the individual. For example, there may be a lack of understanding among employers of concepts of incomplete genetic penetrance, variable expressivity and genetic heterogeneity, and variability of the severity of the genetic condition. Therefore, the worst possible scenario is often used as a standard for policy decision regarding at-risk individuals. See: P.R. Billings et al., "Discrimination as a Consequence of Genetic Testing" (1992) 50 Am J. Hum. Genet. 476 at 476.

77 [1985] 2 S.C.R. 536 at 551. (Hereinafter *O'Malley*)

78 However, see the Human Rights Tribunal in the decision of *Thwaites* v. *Canadian Armed Forces* (1993), 19 C.H.R.R. D/259 which found that the difference between direct and adverse effect discrimination may only be one of semantics. In the case of direct discrimination, the employer must justify its rule or practice by

(b) DISCRIMINATION UNDER THE *CANADIAN HUMAN RIGHTS ACT*

Federally regulated employers in Ontario are governed by the *Canadian Human Rights Act.* Direct employment-related discrimination is prohibited under section 7, which prevents an employer from refusing to employ an individual, or differentiating between employees, on a prohibited ground of discrimination. Section 3(1) lists the prohibited grounds of discrimination as race, national or ethnic origin, colour, religion, age, sex, marital status, family status, disability, and conviction for which a pardon has been granted. Section 10 proscribes constructive discrimination in employment on the same grounds.

"Disability" is defined in section 25 of the Act and covers "any previous or existing mental or physical disability and includes disfigurement and previous or existing dependence on alcohol or a drug". Is this language broad enough to cover discrimination based on genetic test results? In order to be protected by the Act, genetic characteristics may need to be identified as a "handicap" or another enumerated ground. If they are not included specifically in the proscribed grounds of discrimination, the Act does not apply, and an employer could discriminate legally on this basis. Clearly, any manifest genetic disorder could fall under the definition of "handicap" in any of the subsections i) to iv). In the case of *Bicknell* v. *Air Canada,* a manifest genetic disorder, namely an X-chromosome linked to colour blindness, was accepted by both counsel as a disability.[79]

Unlike the Ontario *Code*, "perceived" handicaps are not addressed directly by the Canadian Act. They have, however, been read into the definition of disability.[80] Perceived handicaps can be a source of discrimination, a classic example being HIV infection, which, in its early stages, causes no discernible incapacity, although it may be perceived as such by others. The Canadian Human Rights Commission has issued a policy statement on HIV infection that specifically states that it falls under discrimination on the basis of disability.[81] The more difficult question, however, pertains to whether a "genetic predisposition" would fall under the Act.

Genetically based characteristics of "race", "national or ethnic origin", "colour" or "sex" are all examples of the Act' s protection of various genetic characteristics and predispositions, albeit ones with specific social meanings. Furthermore, mutant genes are often localized in given subsets of the population.[82] A strong argument could be made that

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demonstrating there are no reasonable alternatives and that the rule or practice is proportional to the end being sought. In the case of adverse effect discrimination, the neutral rule is not attacked but the employer must still show it could not otherwise reasonably accommodate the individual disparately affected by that rule. In both cases however, the inquiry is essentially the same: the employer must show that it could not have done anything else reasonable or practical to avoid the negative impact on the individual.

79 (1984), 84 C.L.L.C. 17,006. (But the case never stated that the colour blindness was X-chromosome linked).

80 See *Foucault* v. *C.N.R.* (1981) 2 C.H.R.R. D/475 and *Brideau* v. *Air Canada* (1983) 4 C.H.R.R. D/1314 .

81 Canadian Human Rights Commission, *Policy on AIDS,* (Ottawa: CHRC, 1988).

82 The localization of Tay-Sachs Disease in the Ashkenazi Jew population is a classic example.

discrimination on the basis of genetic predisposition would constitute adverse effect discrimination against a given "race", "nationality or ethnicity", "colour" or "sex".

Due to its vague definition of disability, is not clear whether the Act will be interpreted to prohibit discrimination on the basis of genetic characteristics. Certainly, where a genetic condition manifests itself in the form of a noticeable disorder, the disorder itself will be considered a "handicap". Where a test identifies a genetic predisposition that has not yet manifested itself, it might be considered a "perceived" handicap, a concept that, as mentioned, has been read into the Act. While there is a clear possibility that discrimination on the basis of genetic predisposition would constitute adverse effect discrimination on the basis of other proscribed grounds, a more detailed definition of handicap in the statute itself or a directive from the Canadian Human Rights Commission with regard to what constitutes a perceived handicap might be necessary to clarify some of the ambiguities.

(c) DISCRIMINATION UNDER THE ONTARIO *HUMAN RIGHTS CODE*.

The *Human Rights Code* applies to the private sector and, as such, to the greatest number of employers and workers. Section 5(1) sets out the operative provision in relation to employment:

> 5.—(1) Every person has a right to equal treatment with respect to employment without discrimination because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sex, sexual orientation, age, record of offences, marital status, family status or handicap.

As in the federal statute, both direct discrimination (section 5) and constructive discrimination (section 11) are prohibited on the same grounds. The *Human Rights Code* also contains the most extensive definition of "handicap" of any Canadian jurisdiction.[83] Section 10(1) provides, in part, as follows:

> 10.—(1) In Part I and in this Part,
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> "because of handicap" means for the reason that the person has or has had, or is believed to have or have had,
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> (a) any degree of physical disability, infirmity, malformation or disfigurement that is caused by bodily injury, birth defect or illness and without limiting the generality of the foregoing, including diabetes mellitus, epilepsy, any degree of paralysis, amputation, lack of physical coordination, blindness or visual impediment, deafness or hearing impediment, muteness or speech impediment, or physical reliance on a guide dog or on a wheelchair or other remedial appliance or device,
>
> (b) a condition of mental retardation or impairment,
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> (c) a learning disability, or a dysfunction in one or more of the processes involved in understanding or using symbols or spoken language,

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83 W.S. Tarnopolsky & W.F. Pentney, *Discrimination and the Law* (Toronto: Carswell, 1994, looseleaf) at 9-26.

(d) a mental disorder, or

(e) an injury or disability for which benefits were claimed or received under the *Workers' Compensation Act.*

The specificity of the wording has resulted in relatively few disputes regarding what is a "handicap".[84] In Ontario, a handicap has been construed to mean "something which affects, or is perceived to affect, an individual in carrying out life's important functions".[85] The board of inquiry decided that to call a temporary flu virus a disability would be to trivialize the important goals of human rights legislation. Conversely, it could be argued that a genetic predisposition, with its life-long implications, could be recognized as a handicap.

Ontario law differs substantially from that of other Canadian jurisdictions, in that the above definition in section 10(1) includes both "real" and "perceived" handicaps by virtue of the phrase "believed to have or have had". As we have seen, genetic predisposition could fall under the definition of handicap as a "perceived" handicap. While the person with the predisposition has no discernible incapacity (by definition), the person may be *perceived* to have a disability by potential employers who perform medical tests. Some judicial precedent would reinforce this position. In *Horton* v. *Niagara,*[86] a human rights tribunal stated in *obiter,* that if obesity had genetic origins, then it would be protected by the *Code.*

The rights of the disabled are further elaborated in section 17(1), which provides as follows:

> 17.—(1) A right of a person under this Act is not infringed for the reason only that the person is incapable of performing or fulfilling the essential duties or requirements attending the exercise of the right because of handicap.

Section 17(1) requires that the worker must be "incapable of performing or fulfilling the essential duties or requirements [of the employment]" before the employer's denial of employment is valid. Could an employer ever satisfy this standard in the case of a genetic predisposition or susceptibility? By definition, there are no immediate impediments, the affected employee being fully able to work. In the long term, there is a possibility that the employee's capacity may decline, but even then the prognosis is usually uncertain.

Another enumerated ground of discrimination that might cover the situation of genetically predisposed individuals is that of "ancestry". As it is not defined by the *Code* , it is open for interpretation by the courts. In a New Brunswick case, the courts used the term in relation to the Jewish faith,[87] despite the fact that religious convictions and race are already separate enumerated grounds. To give the term a meaning distinct from the others, it could be

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84 *Ibid.*, at 9-26.3.

85 *Ouimette* v. *Lilly Cups* (1990), 12 C.H.R.R. D/19 at D/33.

86 (1988), 88 C.L.L.C. 17,004.

87 *Attis* v. *New Brunswick School District No. 15* (1991), 86 D.L.R. (4th) 749 (N.B.Q.B.).

argued that ancestry is akin to a familial, inheritable trait. In Quebec, "civil status" is recognized as a ground for discrimination. The concept was elaborated upon in the *Brossard* case, in which a person had been denied employment illegally because a family member was a politician.[88] These types of factors, like genetic characteristics, which are immutable traits passed on by ancestors, are out of the control of the applicant and should perhaps not be determinant in the employee selection process.

With specific regard to pre-employment testing, section 23(2) of the *Code* reads:

> 23.—(2) The right under section 5 to equal treatment with respect to employment is infringed where a form of application for employment is used or a written or oral inquiry is made of an applicant that directly or indirectly classifies or indicates qualifications by a prohibited ground of discrimination.

According to the Commission, this section applies to all forms of testing, including medical and presumably genetic testing. Under section 23(2), any assessment to determine a person's ability to perform a job, including a medical examination, should be done only after a conditional offer of employment is made, to ensure the candidate is assessed purely on his or her merits.[89] If an employer purports to refuse employment based on health factors linked to ability, he or she must be able to present clear, objective and reliable medical and statistical evidence, considering the relevant requirements of the job. If a rejection is made, based on medical evidence only, then the matter is neatly framed for a human rights complaint .

4. DEFENSES TO CHARGES OF DISCRIMINATION

Legal protections against discrimination can never be absolute, as the rights of a certain individual or group must be balanced against the rights of others in Canadian society. As we have seen, even the constitutional guarantees to equality under the *Charter* can be limited by the application of the reasonable means test of section 1. Under human rights law, employers' defences to allegations of discrimination vary depending on whether the *Canadian Human Rights Act* or the Ontario *Human Rights Code* apply. Generally speaking, discrimination can be justified by the employer on the basis that the restriction is a *bona fide* occupational qualification or requirement (BFOQ or BFOR)[90] or by the related concept that it would cause the employer undue hardship to accommodate the worker.

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88 *Brossard (Town)* v. *Québec (Commission des droits de la personne)*, [1988] 2 S.C.R. 279.

89 Ontario Human Rights Commission, *Policy on Employment-Related Medical Information* (Toronto: OHRC, 1991).

90 *Bona fide* occupational requirement and *bona fide* occupational qualification were said to be equivalent and co-extensive by the majority's ruling in *Central Alberta Dairy Pool* v. *Alberta Human Rights Commission,* [1990] 2 S.C.R. 489, at 502. (hereinafter *Central Alberta Dairy Pool)*

(a) Defenses under the Canadian Human Rights Act

The defence of *bona fide* occupational requirement, a concept first elaborated upon in the *Etobicoke* firefighters' age discrimination case,[91] is available to federally regulated employers through section 15(a). The federal government's policy regarding BFOR emphasizes that there are three key issues in determining if a BFOR exists: (1) determining the essential components (tasks) of the job; (2) determining the capacities necessary for safe, efficient and reliable performance of the essential components; and (3) assessing if the individual has the necessary capacities for safe, efficient and reliable performance of the job based on *existing* data, while recognizing that BFOR is a dynamic concept, which changes over time and with developing technology.[92]

In Etobicoke, McIntyre J. set out the requirements for a valid BFOR defence to be upheld, in the following terms:[93]

> To be a *bona fide* occupational qualification and requirement a limitation...must be imposed honestly, in good faith, and in the sincerely held belief that such limitation is imposed in the interests of the adequate performance of the work involved with all reasonable dispatch, safety and economy, and not for the ulterior or extraneous reasons aimed at objectives which could defeat the purpose of the Code. In addition, it must be related in an objective sense to the performance of the employment concerned, in that it is reasonably necessary to assure the efficient and economical performance of the job without endangering the employee, his fellow employees and the general public.

The Supreme Court has thus based its interpretation of BFOR on the ubiquitous twin factors of economic cost and health and safety.

The Supreme Court went further in the case of *Bhinder,*[94] which addressed religious discrimination in the workplace, and ruled that, once a legitimate BFOR is established, a

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91 *Ontario Human Rights Commission* v. *Borough of Etobicoke,* [1982] 1 S.C.R. 202. (hereinafter *Etobicoke*)

92 Canadian Human Rights Commission, *Bona Fide Occupational Requirement Policy* (Ottawa: CHRC, 1988) at 2-3.

93 *Etobicoke, supra,* note 91 at 208. See also *Robinson* v. *Canada (Armed Forces)* (1991) 15 C.H.R.R. D/95 & 21 C.H.R.R. (F.C.A.) D/113 where the court noted that the onus was on the Canadian Armed Forces to show that a blanket "seizure free" epilepsy policy is reasonably necessary, despite the fact that there are four different classifications of epilepsy each with a different risk of employee failure. The possibility of individual testing as a practical alternative to a discriminatory rule should be taken into account when determining whether the rule is reasonably necessary in the circumstances. Also, *Canadian Civil Liberties Association and Canadian Human Rights Commission* v. *Toronto Dominion Bank* (1994) Human Rights Tribunal where the Bank's policy of obliging all new and returning employees to undergo mandatory drug testing was found not "reasonably necessary" as a means to assure job performance, employee health or freedom from criminal activity as it did not apply, on a regular basis to all employees, but rather only once in the career of some employees when they first accept employment. The Tribunal found mandatory urinalysis as a blanket policy intrusive particularly since there was insufficient evidence to indicate a serious threat (of drug dependence/illicit activity) to bank employees, the public or customers.

94 *Re Bhinder and C.N.R. Co.*, [1985] 2 S.C.R. 561. (hereinafter *Bhinder*)

complaint of (adverse-effect) discrimination is unavailable and no duty of reasonable accommodation arises. This decision was much maligned for curtailing substantially the flexibility and reach of the *Act,* particularly for the disabled whose integration into the workplace depends, more than for any other group, on accommodation in its most literal sense.[95] Elements of *Bhinder* were subsequently overturned by *Central Alberta Dairy Pool,* which ruled that the BFOR defense was available only in cases of direct discrimination and that, in all other cases, employers were subject to a duty to accommodate. The recourse to such a defense continues to be substantially limited by a test developed in the *Brossard* case, which states that an overly broad rule cannot be justified as a BFOR.[96] Furthermore, the rule developed in the *Saskatoon Fire Fighters* case still requires that the employer demonstrate that its concerns cannot be addressed by individualized assessments.[97] Thus, with the courts' growing understanding of the need to integrate the disabled into the workplace, it seems unlikely that a BFOR containing a blanket exclusion of workers genetically predisposed to occupational disease would be deemed acceptable under the provisions of the *Act*.. Moreover, the slow judicial expansion of the duty to accommodate seems to indicate that occupational requirements of affected individuals, if any, will be dealt with on an individual and personalized basis.

Both the cost and safety aspects of the undue hardship standard have been elaborated upon progressively by the courts. They require that the current abilities of a disabled person be taken into account, not the aptitudes, needs, or risks that may develop in the future. Unpredictable future possibilities cannot be used to assess needs for accommodation in the present. There are no immediate costs associated with accommodating an employee with a genetic predisposition to disease when there is no current functional disability. Existing case law makes it clear that it will be difficult for an employer to justify the refusal of employment to persons with genetic predispositions simply on the basis of economic concerns.

Of course, as the probability of onset of a disorder increases, so does the potential cost to an employer. However, only in the rarest of cases—as with Huntington's disease, which has an incidence of one in every 10,000 Caucasians[98]—is there a virtual certainty of onset of disease. Where there is uncertainty as to the onset of a disorder, the courts will tend, based upon statements in *Etobicoke* and *O'Malley,* to balance rights in favour of an employee who at the present time shows no incapacity to work. The law pertaining to HIV infection, with its unpredictability regarding the moment of onset of AIDS, will be highly instructive in the development of the law in this area. In the case of a seropositive member of the Canadian Armed Forces, for instance, a tribunal found that discrimination occurred whenever the

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95 See Canadian Human Rights Commission, *Special Report to Parliament on the Effects of the Bhinder Decision* (Ottawa: CHRC, 1986).

96 *Supra,* note 88.

97 *Saskatchewan (Human Rights Commission)* v. *Saskatoon (City)*, [1989] 2 S.C.R. 1297.

98 Science Council of Canada, *supra,* note 5, at 20.

employer considered the disease in the abstract, without having regard to how the individual was actually coping with his affliction.[99]

Furthermore, the statement by McIntyre J. in *Etobicoke* makes it clear that, once a genetic disorder begins to manifest itself and to affect job performance seriously, an employer is, as always, entitled to retire or discharge an employee for cause.[100] As stated earlier, once a genetic disorder manifests itself, it will likely be legally interpreted as a handicap, and discrimination on this basis may be challenged in the conventional fashion.

McIntyre J. expanded on the meaning of undue hardship in an "economic cost" sense. In *O'Malley* v. *Simpson-Sears,* he summarized that reasonable steps short of undue hardship to accommodate the complainant in a case of religious discrimination meant "to take such steps as may be reasonable to accommodate without undue interference in the operation of the employer's business and without undue expense to the employer".[101]

The touchstones of this characterization are expense and organizational efficiency. Madam Justice Wilson stated that the factors relevant to an appraisal of what constitutes undue hardship include financial cost, disruption of a collective agreement, problems of morale of other employees, and interchangeability of the workforce and facilities. She also stated that the size of the employer's operation would be a factor in considering whether the financial cost is undue, or the adaptation is difficult.[102]

It is clear that the identifiable costs of reasonable accommodation that might be borne by the employer must be balanced with the rights of the potential employee, "in the interest of preserving a social structure in which each right may receive protection without undue interference with others".[103] The hardship caused by an accommodative change, in the sense of expense or inconvenience, must be measured in light of the benefits gained by the complainant, and others who are similarly situated, in order to determine whether the particular accommodation imposes an undue burden on the respondent.

The health or safety aspect of the undue hardship test arises where the degree of risk that remains after the accommodation has been made outweighs the benefits of enhancing equality for disabled persons, or where the proposed accommodation creates a potential conflict with a health or safety requirement. If the health or safety requirement has the effect of excluding persons with disabilities, modification or waiver of the health or safety requirement will be necessary unless undue hardship to the employer can be demonstrated. It

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99 *Thwaites* v. *Canada (Armed Forces)*, *supra*, note 78, at D/298.

100 *Supra,* note 91, at 209.

101 *O'Malley, supra,* note 77, at 555.

102 *Central Alberta Dairy Pool, supra,* note 90, at 521.

103 *O'Malley, supra,* note 77, at 555.

is not yet clear how much increased risk to health or safety the disabled worker is expected to tolerate.

The court in *Robinson* v. *Canada (Armed Forces)*[104] discussed the recent history of what constitutes "sufficient risk" as stated by McIntyre J. in *Etobicoke*. Two streams of thought were said to have emerged. The first, exemplified by MacGuigan J. in *Air Canada* v. *Carson,* maintained that "sufficient risk" implies by definition that a certain risk, even if minimal, might be acceptable to ensure the equal opportunity presumably guaranteed by the Canadian Human Rights Act.[105] However, in a number of subsequent decisions, the courts have held that an employer must demonstrate not only that there was a risk, but also that the risk was unacceptable for the employee and the public, for a successful BFOQ defence.[106] This standard was replaced by the second current highlighted in the 1988 decision of *Canadian Pacific Ltd.* v. *Canada* ,[107] where the Federal Court of Appeal replaced its "minimum acceptable risk" test with a test of "real" risk. As such, "sufficiency" as referred to in *Etobicoke* was said to refer to the "reality of the risk, not its degree".[108]

This "real risk" standard, however, has not prevailed. The *Robinson* Court interpreted the *Central Alberta Dairy Pool* decision, discussed above, as a return to the minimum acceptable risk standard, since the "real" risk test was found to be inconsistent with the objectives of human rights legislation.[109] Accordingly, mere identification of risk is not necessarily tantamount to "sufficient risk". The existence of a genetic predisposition would clearly not satisfy the "sufficient risk" standard without an examination of the seriousness of that risk.

The Supreme Court has stated that the burden of proof lay on the employer, and that "statistical and medical evidence based on observation and research" would be of much more persuasive value than "impressionistic" evidence.[110] Madam Justice Wilson has also stated that, "where safety is at issue both the magnitude of the risk and the identity of those who bear it are relevant considerations".[111] The case of *Levac* v. *Canada (Armed Forces)*[112] well illustrates the issue of "sufficient risk" and is adaptable to the issue of genetic discrimination.

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104 *Supra*, note 93, at paragraphs 97-99. (Subsequently appealed on different grounds 21(2) C.H.R.R. (F.C.A.) D/113).

105 (1985) 1 F.C. 209 (C.A.).

106 See for example *McKenzie* v. *Quintette Coal Ltd.* (1986), 8 C.H.R.R. D/3762.

107 [1988] 1 F.C. 209 (C.A.).

108 *Ibid.,* at 224.

109 *Robinson, supra,* note 93, at D/124.

110 *Etobicoke, supra*, note 91, at 212.

111 *Central Alberta Dairy Pool, supra,* note 90, at 521.

112 (1992), 15 C.H.R.R. D/175.

A member of the armed forces was denied a position on a ship due to a potential increased risk of heart disease. A tribunal found that a prediction of an eight to ten percent risk of heart attack over the next five years (or six to nine percent risk over three years on another scale) when balanced against other medical evidence that showed no prior absence from work due to the medical condition, was not of sufficient weight to justify the application of a discriminatory rule or practice that violates the *Canadian Human Rights Act*.[113] To satisfy the test of "sufficient risk" an employer would have to show risk factors more serious than those in *Levac*.

There is seemingly nothing in the case law that would generally permit discrimination in employment on the basis of a genetic predisposition, and much to militate against such permission. The economic cost aspects of undue hardship, as elaborated by the Supreme Court of Canada, require a high standard of proof that is unlikely to be satisfied by reference to persons with a genetic predisposition. As to the question of safety, there is a greater chance that a court will find in favour of an employer, but only where extensive training and public safety are involved, (as in the case of an airplane pilot), and where the health risk identified by the genetic predisposition is severe and no treatment exists.

(b) Defenses under the Ontario *Human Rights Code*

In order to avoid the difficulties inherent in the *Bhinder* decision, Ontario has amended the *Code* to ensure that a duty to accommodate to the point of undue hardship exists regardless of whether discrimination is direct or constructive. Furthermore, it has enacted a specific duty to accommodate disabled individuals. Regarding the handicapped, section 17(2) states:

> 17.—(2) The Commission, a board of inquiry or a court shall not find a person incapable unless it is satisfied that the needs of the person cannot be accommodated without undue hardship on the person responsible for accommodating those needs, considering the cost, outside sources of funding, if any, and health and safety requirements, if any.

Section 11(1), referring to constructive discrimination on the basis of any proscribed ground, provides, in part, as follows:

> 11.—(1) A right of a person under Part I is infringed where a requirement, qualification or factor exists that is not discrimination on a prohibited ground but that results in the exclusion, restriction or preference of a group of persons who are identified by a prohibited ground of discrimination and of whom the person is a member, except where,
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> a) the requirement qualification of factor is reasonable and *bona fide* in the circumstances.

Section 11(2) incorporates the undue hardship test:

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113 *Ibid.*, at D/193.

> 11.—(2) The Commission, a board of inquiry or a court shall not find that a requirement, qualification or factor is reasonable and *bona fide* in the circumstances unless it is satisfied that the needs of the group of which the person is a member cannot be accommodated without the undue hardship on the person responsible for accommodating those needs, considering the cost, outside sources of funding, if any, and health and safety requirements, if any.

Thus the defence of BFOQ is not available unless the employer has attempted reasonably to accommodate the disabled worker. The use of parallel language in the provisions indicates the legislature's intent to eliminate the controversy provoked by the ruling in *Bhinder* and to focus the legal standard of "undue hardship" once again upon economic cost factors and health and safety factors, regardless of whether the discrimination is of the direct or adverse-effect form.

While much of the jurisprudence on the economic and safety aspects of undue hardship cited earlier applies here, it should be noted that the Human Rights Commission of Ontario has developed guidelines for assessing the accommodation requirements of disabled persons, which, while they have no legal force, are cited as the vanguard with regard to the duty to accommodate and will no doubt serve to guide boards of inquiry and courts at least within the province.[114] While sometimes proposing stricter standards than the courts, the guidelines echo much of the jurisprudence and provide a useful overall picture of how evaluations of cost and risk should ideally be made.

According to the Commission, cost factors should be evaluated in light of expenditures and subsidies ("outside sources of funding, if any") such as tax deductions created as incentives to hire disabled workers. Undue hardship will result only if expenditures are "so substantial that they would alter the essential nature of the enterprise or so significant that they would substantially affect the viability of the enterprise".[115] Evaluation of safety and health factors should take into account the willingness of the disabled person to assume the risk, where his or her safety or health could be affected and whether modifications or waivers of safety norms are likely to result in a serious risk for other individuals.[116] The seriousness of the risk should be considered in light of its nature, severity, probability and scope.[117]

In 1993, the Royal Commission on New Reproductive Technologies wrote as follows:[118]

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114 Ontario Human Rights Commission, *Guidelines for Assessing Accommodation Requirements for Persons with Disabilities Under the Ontario Human Rights Code,1981, as Amended,* (Toronto: OHRC, 1989)

115 *Ibid.*, at 7.

116 *Ibid.*, at 12.

117 *Ibid.*, at 13.

118 Royal Commission on New Reproductive Technologies, *Proceed with Care,* vol. 2 (Ottawa: Minister of Government Services Canada, 1993) at 869.

> One gap in human rights legislation is that a genetic susceptibility to a late onset disorder might not be perceived by the law as a disability, and so such people may not have protection. [T]here appears to be considerable protection against discrimination in employment on the basis of genetic information. We recognize, however, that if genetic testing of adults comes into wider use, these protections could be challenged or eroded. For example, employers might seek to expand the definition of bona fide occupational requirements by claiming that the presence or absence of a given genetic trait would indicate a person's unsuitability for a particular job and to justify testing on this basis.

Unlike their counterparts in the United States, Canadian employers, who benefit from a universal health care system, will rarely suffer direct health care costs related to employing persons with genetic predispositions. Nonetheless, existing law will force employers to accept other expenses associated with genetic diseases such as pension plan costs and retraining costs. However, balanced against a complete prohibition of employment for certain individuals who have only a probability of contracting or developing disease, interpretation of the legislation and existing case law would suggest that the courts will generally favour employees. Policy makers and judges should, however, remain on the lookout for the type of erosion of legal protections raised by the Commission.

While genetic testing and monitoring of workers raises a number of human rights issues, at present the most pressing may be the right to privacy.[119] Of growing concern is how results from tests performed in an occupational setting will be handled by workers, management, and health professionals. The potential for breaches of confidentiality in a context in which labour and management diverge on the goals and application of genetic testing may be much greater than in other health care situations.

5. CONFIDENTIALITY OF AN EMPLOYEE'S GENETIC INFORMATION

The question of employer access to genetic information and, in this context, the crucial obligations of an employer's occupational physician are examined, in turn, below.

(a) Acquisition of Genetic Information by Employers

There are a number of situations in which an employer may be obliged to acquire and handle genetic information about its workers. As we have seen, under section 23(2) of the *Code*, medical assessments of a person's ability to do a job should be performed only after a conditional offer of employment is made. In these situations, applicants must answer questions when asked if they suffer any handicap that would prevent them from doing the job. How should they respond if they have a genetic predisposition that they consider benign? In Quebec, it has been suggested that an employee has an obligation to disclose genetic information when a genetic predisposition or susceptibility is: (1) known by the applicant (or employee); (2) particularly significant regarding the job; (3) probable to occur or of sufficient certainty to occur; and (4) sufficiently serious to affect the ability of the applicant (or

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119 For an exhaustive examination of these issues see *infra*, ch. 9.

employee).[120] Unless all of the above criteria are satisfied, it is suggested that no disclosure should be required. Under workers' compensation legislation, if at the time of entering into employment, an employee makes a wilful and false representation as to previously suffered diseases, a claim for compensation benefits could be jeopardized.[121] However, because genetic predisposition is currently not a disease *per se*, it may fall outside the compulsory disclosure requirement.

It has been recommended that pre-employment medical examinations should relate only to the question of the worker's ability to perform the job, not the complete medical history of the employee, unless such an examination is part of a medical program, either as mandated by legislation or an employer's voluntary monitoring of occupational hazards and diseases. The obligation to disclose medical information was examined in *Rapson* v. *Stemms Restaurants and Sipsis.*[122] While declining to detail the full implications of section 23(2) regarding when disclosure is required, the court stated that the employee's epilepsy posed no threat to himself or others, and did not interfere with his ability to perform the essential duties of his job.[123]

Brief mention must be made of the "implicit coercion" to communicate medical information or to submit to testing that may exist in employment situations. While applicants and employees technically have both the common law power to refuse medical testing as well as the protection of the *Human Rights Code* against certain types of tests,[124] the practical effect of such rights in the workplace is uncertain, particularly when a refusal could mean losing out on a job opportunity. Implicit coercion could result when jobs are scarce or when workers are not otherwise able to use legal remedies. This continuing dilemma of employer-employee relations is a topic of potential interest to the legislature. The employer may believe that medical information is relevant to the efficient and profitable conduct of their business.[125] Also, employers often claim that ownership of records entitle them to control and have access to the medical records.[126]

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120 See H. Guay, B.M. Knoppers & I. Panisset, "La génétique dans les domaines de l'assurance et de l'emploi" (1992) R. du B. 185 at 266; Of the four criteria proposed for requiring disclosure by Quebec workers, it would seem to be the third, pertaining to the probability of occurrence, that is most significant. Applicants for safety-sensitive jobs would have a higher onus to disclose.

121 *Workers' Compensation Act,* R.S.O. 1990, c. W.11, s. 134(1).

122 (1991) 14 C.H.R.R. D/449.

123 *Ibid.,* at D/460.

124 This applies both during pre-employment testing and during the course of employment, under s. 23(2) and s. 5 of the *Code.*

125 Natowicz et al., *supra,* note 74, at 467.

126 *Krever Commission Report, supra,* note 2, vol. 3, at 168.

With regard to testing during the course of employment, employer-run medical programs are established either voluntarily (for the company's or worker's benefit),[127] or by obligation under the *Occupational Health and Safety Act.*[128] Under the *Act,* a number of broadly worded provisions oblige virtually all employers to undertake certain duties.[129] Under sections 23 and 25, constructors and employers have the duty to ensure the protection of workers. Section 26 requires that an employer establish a medical surveillance program and to provide for safety-related medical examinations and tests as prescribed, both for the benefit of workers.

It is not known if any Canadian employers are currently using genetic testing under the authority of the above sections. However, as technology moves ahead, new tests and more refined tests for predispositions to occupational and other types of diseases may become available. The existence of such tests may imply an obligation on certain employers to use them, as they may constitute, for example, a "precaution reasonable in the circumstances" as required by section 25(2)(h) of the *Act.* Similarly, regulations may be introduced pursuant to section 26(1)(h)(i), in particular industries, such as the chemical industry, that would require the monitoring of workers who may be exposed periodically to carcinogens, in order to protect the workers who are genetically most susceptible.

Under section 28(3), an employee is not required to participate in a medical surveillance program unless he or she consents to do so. This provision reflects the basic common law principle that "every human being of adult years and sound mind has a right to determine what shall be done with his own body".[130] Legislation that does not respect an individual's power of consent would likely infringe the right to "security of the person" in section 7 of the *Charter,* as it has been held that the "common law right to determine what shall be done with

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127 See *Martin Entrop* v. *Imperial Oil Limited* (1995) Board of Inquiry (Human Rights Code) Decision No. 95-038 where the Ontario Human Rights Commission ruled that while companies have a legitimate interest in implementing drug testing programs (to prevent workplace accidents), they are not entitled to probe into the employees past. Entrop, a senior operator at Imperial Oil was demoted in 1991 after revealing under a new policy that he had been treated for alcoholism in 1984, although he had not had a drink in seven years. He was later reinstated subject to medical screening, psychological assessment and agreeing to a series of random breath-analysis tests. The decision of the Commission raises doubts as to the propriety of random, mandatory tests. In considering the appropriate role for drug testing, the challenge is to strike a balance between the legitimate requirements of health and safety and the individual's right of privacy. Although the court did not address the issue of the future implications of genetic testing, the decision may go a long way in preventing pervasive genetic testing under the guise of health and safety. See also commentaries on this case: "The Limits of Drug Testing" The Globe and Mail, June 29 1995; "Imperial Oil Alcoholism Ruling Backed: Firms have right to prevent work accidents, but not to probe employees' past, lawyers say" The Globe and Mail, June 28 1995, B3; "Alcoholism Ruled No Bar to Job" Toronto Star, June 27 1995, A3; "Imperial Oil Alcoholism Rule Struck Down: Policy requiring disclosure called illegal" The Globe and Mail, June 27 1995, B1; "Drug Testing Challenged" The Globe and Mail, June 8 1995, A2.

128 *Supra*, note 3.

129 Employers of farm workers are generally exempted, unless added by regulations: s. 3(2).

130 *Schloendoff* v. *Society of New York Hospital* (1914), 211 N.Y 125. The power of consent to treatment was recently reaffirmed in *Malette* v. *Shulman* and *Fleming* v. *Reid*, *supra*, note 61 and in the criminal context, in *R.* v. *Dyment* and *R.* v. *Dersch, supra,* note 70 and *R.* v. *Greffe*, [1990] 1 S.C.R. 755.

one's own body and the constitutional right to security of the person can be treated as co-extensive".[131] Statutorily mandated medical programs are therefore voluntary on the part of the employee. The common law protection of power of consent also applies to voluntarily administered company medical programs. Thus, in theory, an employer will obtain genetic information only with the freely given consent of a worker.

Understandably, employees have serious concerns regarding the use of genetic information once it finds itself in the hands of an employer. First, there is a fear that, although genetic monitoring is intended to be a specialized form of medical monitoring, it still enables an employer to obtain genetic profiles of his or her employees, and may be used as a disguised screening program. Second is the fear that employers will use the results of monitoring to dismiss workers who show signs of being affected by the work environment, or to move an affected worker to a position with decreased benefits. Third, there is concern that employers may decide, or regulations may stipulate, that a worker with a history of exposure to a particular substance is not suitable for a job that will subject him or her to further exposure. Fourth, there is the possibility that employers (previous and prospective) may share medical information, either by directly sharing records or genetic test results, or by circulating lists of employees who have filed work-injury law suits (as indicative of workers who may have genetic or other susceptibilities). And finally, employees may have difficulty documenting such practices.[132]

(b) The Obligations of the Company Occupational Physician

What are the obligations of a company occupational physician to employees, to employers, and to outside parties?[133] Traditionally, doctors have been bound ethically to maintain all confidences with their patients, as required by the Hippocratic Oath. However, one of the purposes of company-organized medical programs is to give management an assessment of the health status of the workers. The *Krever Commission Report* noted that "[t]here is substantial evidence that often pressure is exerted on health professionals to disclose information to the employer".[134] How carefully guarded is employer-held medical information? Is the company occupational physician in an irresolvable conflict of interest?

The legislature has made very little foray into regulating the flow of medical information held by private doctors, nurses, or company occupational physicians. The *Freedom of Information and Protection of Privacy Act,*[135] which governs access to

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131 *Fleming* v. *Reid, supra,* note 61, at 88.

132 Holtzman, *supra,* note 11, at 205.

133 For further discussion of this issue see: U.S. Congress Office of Technology Assessment, *The Role of Genetic Testing in the Prevention of Occupational Disease* (Washington D.C.: Government Printing, 1983) at 115. (hereinafter *1983 OTA Report*)

134 *Krever Commission Report, supra,* note 2, vol. 3, at 160-61.

135 R.S.O. 1990, c. F.31.

information within the government and designated institutions,[136] does not apply to the private sector.[137] It does not extend to private physicians, private sector hospitals,[138] university research laboratories, genetic centres, or private laboratories. Other legislation exists that mandates the keeping of records, and sometimes access to information in certain public institutions.[139] However, as noted by the *Krever Commission Report,* of the seventy-seven pieces of legislation that governed the confidentiality of medical information in Ontario at that time, "the whole is not greater than the sum of its parts".[140]

With regard to genetic testing, similar concerns have been echoed by the Information and Privacy Commissioner of Ontario. A report entitled *Workplace Privacy: The Need for a Safety-Net* :recommends that workers who consent to testing retain absolute control over the use and disclosure of the resulting genetic information.[141]

For the moment, confidentiality of the vast realm of medical information held privately in Ontario is governed only by common law rules of ambiguous application in the medical context,[142] codes of ethics, and disciplinary regulations that apply to health professionals.[143] For example, the *Code of Occupational Medical Ethics* enunciates the duty to respect the confidentiality of medical information, by treating as confidential, any medical information learned about the employee, and releasing the information only in accordance with acceptable medical practice.[144] This suggests that the occupational physician does not have a duty to warn the employer of incidental findings that are not pertinent to the ability of the employee to fulfill the job requirements in question.

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136 Listed in R.R.O. 1990, Reg. 460.

137 Section 2(1).

138 The vast majority of hospitals are not covered by the *Act*; however, a small number of special hospitals, with particularly close government administration do fall under the *Act*. This includes 11 psychiatric hospitals which, by s. 6 of the *Mental Hospitals Act,* are under the direct administration of the Ministry of Health.

139 See for example, the following: *Charitable Institutions Act,* R.S.O. 1990, c. C.9, at (R.R.O 1990), Reg. 69, s. 29; *The Community Psychiatric Hospitals Act,* R.S.O. 1990, c. C.21, at Reg. 91 ss. 21, 22(2); *Public Hospitals Act,* R.S.O. 1990, c. P.40, s. 11 & Reg. 965, ss. 19, 21; *Homes for Special Care Act,* R.S.O. 1990, c. H.12, at Reg. 636, s. 36; *Homes for Retarded Persons Act,* R.S.O. 1990, c. H.11, at Reg. 635, s. 21; *Mental Health Act,* R.S.O. 1990, c. M.7, ss. 9(2), 35(2), 35(3); *Nursing Homes Act*, R.S.O. 1990, c. N.7, at Reg. 832, ss. 88, 89, 95; and the *Private Hospitals Act,* R.S.O. 1990, c. P.24, ss. 21, 33(i).

140 *Supra*, note 2, vol. 1, at 51.

141 Information and Privacy Commissioner, *Workplace Privacy: The Need for a Safety-Net* (Toronto: IPC,1993) at 7.

142 S. Rodgers-Magnet, "Common Law Remedies for Disclosure of Confidential Medical Information" in the *Krever Commission Report, supra,* note 2, vol. 3, at 297.

143 For example: L'Association des Médecins du Travail du Québec, *Guide de Pratique* (Document de Travail, Nov. 1991); Canadian Medical Association, *Code of Ethics* (Ottawa: CMA, 1990); Occupational Medical Association of Canada, *Code of Occupational Medical Ethics* (London, Ontario: OMAC, 1989).

144 See *infra*, ch. 9.

The occupational physician is under no statutory obligation to divulge specific medical conditions to company management. Statutory limits come into effect only when the employer begins to make decisions on grounds that contravene the *Human Rights Code.*[145] Only the ethical duties of the occupational physician limit what may be told to management. The *Code of Occupational Medical Ethics* states that the physician should communicate only a recommendation to the employer regarding fitness to perform a specific job and should provide the employer with relevant medical details or diagnosis only when permitted or requested to do so in writing by the employee.

In the case of *A.G. Quebec and Keable* v. *A.G. Canada,* Mr. Justice Pigeon of the Supreme Court of Canada expressed his opinion that an employee's loyalty to his or her employer does not permit an employer to compel a professional employee to breach his or her duty of confidentiality. He stated that "[t]he medical director of a hospital cannot release a doctor from his obligation of confidentiality towards his patient, only the latter may release him from his duty".[146]

The *Krever Commission Report* made thirty-five specific recommendations pertaining to the control of medical information in the workplace, focusing primarily on protecting employee rights. An overall recommendation was that legislation be enacted to clarify that the professional employee's duty of confidentiality transcends his or her duty to an employer.[147] Two recommendations (Nos.120 &121) echo the *Code of Occupational Medical Ethics*, by suggesting that only information regarding fitness for employment can be given to a prospective employer after a pre-employment medical examination and that limitations on an applicant's fitness be stated without disclosing the medical reason. A third recommendation (No.122) proposes that medical information kept on site not be available to the employer except as permitted by the two above recommendations.[148] The *Krever Commission Report* also expressed uncertainty as to whether most part-time industrial physicians recognized their relationship with the company's employees to be one of physician-patient.[149]

With regard to the occupational physician's duties to outside parties, a potential employer is allowed to request information from a former employer, although the latter is not obliged to give any such information.[150] Is the sharing of medical information on an employee a breach of confidentiality? It is not clear whether management, having access to medical information, is bound by doctor-patient confidentiality. The Krever Commission

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145 An employer who acquires information which contravenes the *Code* leaves himself or herself open to the allegation that employment decisions are being made on grounds proscribed by the *Code*.

146 [1979] 1 S.C.R. 218 at 250.

147 *Krever Commission Report, supra,* note 2, vol. 3, at 168.

148 *Ibid.*, at 186-7.

149 *Ibid.*, at 166.

150 Christie, England & Cotter, *supra,* note 1, at 63.

recommended that legislation be enacted to prohibit an employer from revealing any health information regarding a present or former employee to a third party without the consent of the employee, unless otherwise required by law.

These recommendations have yet to be addressed specifically by the Ontario Legislature, although the Ministry of Health has been developing a proposal for a uniform bill on health care information access and privacy since 1991.[151] This legislation would apply to both private and public sector employers holding health information on individuals and would include specific sections on the duties and obligations of occupational physicians and on employer access to confidential medical records.

Quebec has already extended protection of privacy to the private sector.[152] Article 37 of the new *Civil Code* provides that any person who compiles a medical file on another person must have a serious and legitimate interest, and must take care not to interfere with the reputation and private life of the other. In 1993, the National Assembly adopted an *Act Respecting the Protection of Personal Information in the Private Sector*,[153] which elaborates on the rights and obligations resulting from this and related provisions of the *Civil Code of Quebec* and pays particular attention to the collection, holding, use or communication of personal information by private sector enterprises.

Evidently, the deficiencies of the law relating to medical confidentiality noted by the Krever Commission persist and may even be exacerbated with the advent of genetic testing. The legal obligations of an occupational physician toward employers, employees, job applicants, and outside parties need to be clarified. The time is obviously ripe for a statute that would govern access to medical and genetic information in both the private and public employment sectors of Ontario.

6. CONCLUSION AND RECOMMENDATIONS FOR REFORM

Although Canadian employers currently conduct little if any genetic testing, in the future, genetic test results may well be used in the employment setting to make hiring, promotion, and specific job placement decisions. Employers may also be interested in knowing genetic information about their prospective or current employees in order to determine those who are at increased risk of disease and thus more likely to incur expenses resulting from sick days and disability benefits.

Genetic monitoring for increased susceptibility to workplace exposures, when in accordance with human rights legislation and *bona fide* occupational requirements, may be acceptable as its intended aim is to protect employees. Genetic monitoring however, which

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151 Personal communication of G. Bentivegna, Ontario Ministry of Health, July 1991.

152 Art. 37 C.C.Q.

153 L.Q. 1993, c. 17.

predicts higher risk of disease in general, is clearly aimed only at the financial protection of employers, and is thus offensive to the spirit of human rights legislation.

Current human rights legislation may be sufficiently broad to protect individuals suffering from manifest genetic conditions as well as those suffering from genetic susceptibility or predisposition. Specific legislation targeting genetic discrimination in the workplace may not be warranted if Human Rights Commissions issue interpretative rules regarding the extent to which genetic conditions are given protection.

While employers have a legal obligation to protect the health and safety of their workers, and to conduct appropriate and scientifically available testing, such testing could legitimately be required. Employers have the burden of proving an employee's unsuitability and must justify testing accordingly.

The issues addressed illustrate not only the complexity of the problems that are raised, and will continue to be raised as the use of genetic testing in the employment context becomes more pervasive, but the degree to which current law provides protection against discrimination and breaches of confidentiality. Whether or not workplace genetic testing is to become a widespread practice in Ontario, reflection as well as open discussion and debate on the question of genetic testing should be undertaken by policy makers and other interested parties. Accordingly, the Commission recommends that the Human Rights Commission should issue an interpretive rule providing that genetic conditions, both present and future, fall within the ambit of its legislative protection, rendering the need for specific amendments to the Ontario *Human Rights Code* unnecessary. The Commission further recommends that the definition of the phrase "because of handicap" contained in section 10(1) of the *Human Rights Code* should be amended to add the words "or for the reason that it is believed that the person will have" to the definition, such that the definition will provide as follows:

10.—(1) In Part I and in this Part,

....

"because of handicap" means for the reason that the person has or has had, or is believed to have or have had, or for the reason that it is believed that the person will have,

(a) any degree of physical disability, infirmity, malformation or disfigurement that is caused by bodily injury, birth defect or illness and without limiting the generality of the foregoing, including diabetes mellitus, epilepsy, any degree of paralysis, amputation, lack of physical coordination, blindness or visual impediment, deafness or hearing impediment, muteness or speech impediment, or physical reliance on a guide dog or on a wheelchair or other remedial appliance or device,

(b) a condition of mental retardation or impairment,

(c) a learning disability, or a dysfunction in one or more of the processes involved in understanding or using symbols or spoken language,

(d) a mental disorder, or

(e) an injury or disability for which benefits were claimed or received under the *Workers' Compensation Act.*

In this manner, "perceived disability" would clearly apply to both genetic susceptibility as well as genetic predisposition, without distinction as to present or future handicap. At present, the *Human Rights Code* covers genetic susceptibility; however, in spite of its extensive definition of handicap, it is unclear whether it would protect individuals with predispositions to genetic illness, since perception of disability could be interpreted as a concept temporally grounded in the present. With a genetic predisposition, the discriminatory act occurs in the present, but it is based on a perception of the future. The proposed amendment would thus prohibit an employer from claiming that he did not discriminate on the basis of a perceived disability, but simply favored healthy job candidates who had a lesser risk of being disabled in ten years time.

The Commission recommends that pre-employment genetic testing should be undertaken only when it is demonstrated to be directly job-related. Testing for genetic predisposition as part of job selection criteria and monitoring of workers on the basis of genetic criteria are rejected as reasonable grounds for testing. Testing should be conducted only after a conditional offer of employment is made. The employer would then be required to justify the relationship between the use of a particular (genetic) test and a *bona fide* occupational requirement. Criteria should be established in order to determine when individual genetic pre-employment testing is appropriate, and should include a high standard of proof that the test used is related to a *bona fide* occupational requirement.

The Commission further recommends that specific and informed consent should be required before any type of genetic testing is performed on a worker or job applicant. Employers should be required to disclose the nature and purpose of all medical procedures performed, and to provide genetic counselling services to those who elect to undergo testing.

Any situation, in our view, that discriminates, actually or potentially, against employees having a "genetic or other medically identified predisposition to an impairment," should be considered a violation of the existing rules prohibiting discrimination, and we so recommend. However, any modification to human rights legislation regarding the addition of genetic predisposition, susceptibility, or other condition, is problematic since such an amendment could contribute to public perceptions of various genetic traits as "abnormalities" and to the stigmatization of carriers and susceptible or predisposed individuals.

The Commission recommends that the Ontario Workplace Health and Safety Agency, based on the *Human Rights Code*, should designate which genetic tests are scientifically valid and accurate in a given employment context, in order to avoid indiscriminate use of testing by employers. The employer would still be required to establish that a particular test was relevant and met a *bona fide* occupational requirement before such a test could be certified by the Agency as appropriate in the circumstances. The tests, therefore, should be highly relevant to health problems encountered in the particular area of activity in question, or used to detect genetic susceptibility to toxic substances. This measure would preclude employers from justifying unnecessary or inappropriate testing of its workers as "a precaution reasonable in the circumstances," a blanket provision found in section 25(2)(h) of the *Act.* Approved and designated tests should be included in relevant regulations, and guidelines as to how testing programs are to be administered should also be established.

Finally, the Commission recommends that a uniform bill on health care information access and privacy should be enacted, which would apply to private and public sector employers, and outline clearly the duties of occupational physicians as well as the rules governing employer access to health information, as recommended by the (1980) Krever Report.

CHAPTER 8

MEDICAL TESTING

1. INTRODUCTION

Given the potential magnitude and diversity of genetic testing, any discussion of the legal aspects of such testing must be placed within both the context of medical malpractice trends generally,[1] and the more specific environment of "reproductive" torts.[2] The traditional fundamental rules of medical malpractice liability, based on the concepts of fault and negligence, still apply to medical testing for genetic purposes. What has changed is the possible scope of liability; as the availability of genetic information grows, issues regarding the duty to convey information, how much, to whom, and under what circumstances, arise.

Increased use of ultrasound and increased knowledge of embryonic and foetal development has made pregnancy more visible to the physician and the parents.[3] Although the Supreme Court of Canada ruled in 1989 that the foetus is not a legal person,[4] technological developments continue to make the foetus a medical reality. The growing number of genetic tests will determine not only the possibility of bearing a child affected with a genetic disorder, but also whether a foetus suffers from a serious genetic disease, thus providing both pre-conception and post-conception information.

Of particular concern is whether individuals will have access to, and be free to use, the genetic information available according to their own reproductive wishes. The issue of access relates to whether physicians are obligated to inform individuals about the availability of genetic tests or prenatal screening; the issue of use relates to whether individuals may act on

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1 E. Picard, G. Robertson, *Legal Liability of Doctors and Hospitals in Canada,* 3d ed. (1996), Forthcoming; See also "Special Edition: Professional Norms in the Practice of Human Genetics" (1995) 3 Health Law Journal; R. Pritchard, *Liability and Compensation in Health Care* - A Report to the Conference of Deputy Ministers of Health of the Federal/Provincial/Territorial Review on Liability and Compensation Issues in Health Care (Toronto: University of Toronto press, 1990); P. Deschamps et al., *Report on Health Care Liability in Canada*, Quebec Centre for Private and Comparative Law, (Montreal: McGill University, 1989).

2 See in particular, Royal Commission on New Reproductive Technologies, *Overview of Legal Issues in New Reproductive Technologies* Research Studies; no. 3 (Ottawa: Supply & Services Canada, 1993); *Legal and Ethical Issues in New Reproductive Technologies :Pregnancy and Parenthood* Research Studies; no. 4, (Ottawa: Supply & Services Canada, 1993) (hereinafter Research Studies no. 4).

3 Royal Commission on New Reproductive Technologies, *Proceed with Care*, vol. 2 (Ottawa: Minister of Government Services Canada, 1993) (hereinafter *Proceed with Care*).

4 *Daigle* v. *Tremblay*, (1989) 2 S.C.R. 530, 62 D.L.R. (4TH) 634, 103 N.R. 81, 27 Q.A.C. 81 (Que. C.A.).

such information in pre-conception, pre-implantation, or prenatal screening.[5] Issues of malpractice—including the appropriate standard of care and the duty to disclose—informed consent, and parental liability, all come into play.

The presence of a universal health care infrastructure must also be taken into account when assessing current trends in liability for medical testing and its impact on genetic testing. Although little mention is made of the possible impact of medical testing on physician or parental duties, other than with respect to privacy and confidentiality issues,[6] the absence of any discussion of liability in the policy positions of foreign jurisdictions belies its importance.

At the international level, the World Medical Association adopted basic guidelines on medical liability covering issues of autonomy, disclosure of information and medical secrecy,[7] and the Council of Europe in its 1990 Recommendation on prenatal genetic screening, diagnosis and associated genetic counselling,[8] and again in its 1992 recommendations,[9] set out "Rules for Good Practice" covering issues of disclosure of information, quality of services, counselling, access and self-determination. Likewise, the 1993 Nuffield Council report of the United Kingdom emphasized the importance of voluntariness, counselling, and obtaining an adequately informed consent. According to the Council, the latter should "include information about the implications for other family members" and should be delivered in both written and oral form.[10] The Council recommended that special safeguards should be put in place for minors and for the mentally ill.[11] The absence of further discussion on liability in the United Kingdom may well be due to the fact, however, that, with regard to potential liability for failure to test or for "fault" during testing, the 1976 *Congenital Disabilities (Civil Liability) Act* prohibits suits by children against the physician in the absence of liability to the mother and also prohibits suits by children against their mother for prenatal injury resulting from the mother's negligence in the prenatal regime.[12]

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5 A. Robertson, "The Potential Impact of the Human Genome Project on Procreative Liberty" in G.J. Annas & S. Elias (eds.,) *Gene Mapping: Using Law and Ethics as Guides* (New York: Oxford University Press, 1992) 215 at 216.

6 See *infra,* ch. 9.

7 World Medical Association, *Declaration on the Human Genome Project*, adopted by the 44th World Medical Assembly, Marbella, Spain, September 1992, in (1993) 44:1 IDHL, 150.

8 Council of Europe, Committee of Ministers, Rec. No. R. (90) 13 on Prenatal Genetic Screening, Prenatal Genetic Diagnosis and Associated Genetic Counselling (1990), in (1990) 41:4 IDHL 615-624.

9 Council of Europe, Committee of Ministers, Rec. No. R (92)3 on Genetic Testing and Screening for Health Care Purposes (1992) [hereinafter Council of Europe R (92)3], in (1992) 43:2 IDHL 284-289.

10 Nuffield Council on Bioethics, *Genetic Screening Ethical Issues* (London, 1993), Rec. 4.29 at 40.

11 *Ibid.,* Rec. 4.23 at 27.

12 (U.K.), 1976, c. 28; See Law Commission, *Report on Injuries to Unborn Children* (London: Her Majesties Stationary Office, 1974) at 25-26.

The general lack of discussion of traditional liability issues underscores the fact that, for the most part, physician liability for medical testing will centre on confidentiality issues in those countries with universally accessible health care; that is, countries in which the accessibility and availability of genetic tests are determined as part of larger national, health policy considerations. Furthermore, until the last decade, the doctrine of parental immunity (to say nothing of social policy issues) has served to stem possible parental liability.

In contrast to the European positions, the 1994 report of a committee of the Institute of Medicine of the United States recognized that:[13]

> [Where there is no universal health care insurance] successful litigation against physicians for failing to provide prenatal tests probably accelerated the adoption of some genetic tests and may induce physicians to adopt tests whose limitations are unclear to them. The committee would hope that prospective standard setting—and making physicians aware of such standards—will reduce the chance of poor practices and, consequently, of liability suits.

From this brief summary of foreign policy positions, it is evident that, with the exception of privacy and confidentiality issues,[14] the debate on the legal consequences of medical testing will centre on both the duty of care generally and on issues raised by the genetic testing of vulnerable populations. Indeed, the physician-patient relationship and the parent-child relationship create specific obligations in the context of medical testing. The ambit of the physician's standard of care, and the extent of the obligation to inform, test, and follow-up; the duty owed to patients who do not have full legal capacity (special populations); and the effect of genetic testing information on parental duties to children not yet conceived or to the fetus are considered in turn below.

2. STANDARD OF CARE

"Medical malpractice...encompasses errors of omission and commission by health care professionals that fall below the normal, or appropriate, standard of care."[15] Injury following medical diagnosis or intervention is not necessarily actionable. Like other professionals, physicians are not liable for a mere error of judgment.[16] To be successful in a medical

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13 Committee on Assessing Genetic Risks, Institute of Medicine, Lori B. Andrews *et al.* (eds), *Assessing Genetic Risks: Implications for Health and Social Policy*, (Washington D.C., National Academy Press, 1994) at 50-51. With respect to the legal duties of *investigators* involved in genetic research, according to a 1993 report from the United States, Office for Protection from Research Risks, "a legal duty of investigators to inform subjects about the existence of genetic defects has not been firmly established." Office of Protection from Research Risks, National Institutes of Health, *Protecting Human Research Subjects: Institutional Review Board Guidebook*, Chapter H, "Human Genetic Research" (Washington D.C.: U.S. Government Printing Office, 1993) at 5-53.

14 See *infra*, ch. 9.

15 N. Sharpe, "Psychological Aspects of Genetic Counselling: A Legal Perspective" (1994) 50 Am. J. Hum. Genet.. 234 at 235.

16 Picard, Roberston, *supra*, note 1.

malpractice suit, a patient must establish a duty of care, a breach of that duty, an injury, and a causal link between the breach and the injury.[17]

The practice of medical genetics involves counselling and testing, the elicitation and interpretation of individual and family histories and test results, interviewing, and knowledge of health care referral resources.[18] In order to determine the existence of genetics malpractice, it is thus necessary to consider the competence of the physician performing genetic testing, the standard of care to be exercised in the fulfillment of the duty to test and inform, the duty to follow-up, and, the duty of supervision for those under one's control.

(a) COMPETENCE

According to the 1991 Canadian Science Council report on genetics services, there is a dearth of both qualified medical geneticists and genetics counselors in Canada.[19] Yet, any physician offering genetic testing, performing genetic testing, or providing genetics counseling will be held to the standard of care as determined by the regulations and statutes setting standards of conduct, the case law, the testimony of experts, the standards set by professional bodies,[20] and finally, the guidelines found in generally accepted texts.[21]

That same standard of care applies even where the physician is not a medical geneticist but a general practitioner,[22] an obstetrician performing the tasks of a medical geneticist, or a

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17 *Ibid.*

18 See *supra,* ch. 2.

19 Science Council of Canada, *Genetics in Canadian Health Care* (Ottawa: Supply & Services Canada, 1991) at 58-59. "The 1985 manpower survey conducted by the Canadian College of Medical Geneticists (CCMG) recognized an immediate shortfall of 34 full-time-equivalent (FTE) positions. Canadian health care personnel delivering genetic services consisted of: 43 FTE medical geneticists; 40 FTE "other professional staff". The CCMG estimated the personnel required to provide adequate genetic services at: 65 FTE medical geneticists; 52 FTE other professionals. The survey also predicted that an additional 43 FTE positions would be necessary by 1991. The need for trained medical geneticists and other genetics professionals will continue to grow rapidly as genetics-related technology and health care applications increase."

20 In Canada, the accrediting body is the Canadian College of Medical Geneticists, a college that also has set practice guidelines in some areas (e.g. DNA banking, see *infra* , note 26). Although CCMG guidelines have been developed, consensus on practice standards is still incomplete, see J. Clarke, "Professional Norms in the Practice of Medical Genetics" (1995) 3 Health Law Journal 131 at 141-2. However, see T. Caulfield, "The Practice of Human Genetics: Emerging Areas of Consensus" (1995) 3 Health Law Journal 307-320 where a preliminary effort to develop such a consensus was initiated. See also M. Kuback, "Lessons from the Past" (Presented at the 44th Annual Meeting of the American Society of Human Genetics, Montreal, Canada, October 19, 1994) who noted that litigation was a major driving force in the development of practice standards for clinical genetics.

21 Canadian Health Facilities Law Guide (Don Mills, Ont,: CCH Canadian Limited, 1993) para. 1005.

22 We are headed in the direction of primary (family) physicians having to assume more professional responsibility with respect to genetic knowledge, testing, and counselling, given for example, the advent of genetic screening programs for the identification of individuals at high risk for familial cancer. See J. Clarke, *supra*, note 20 at 43 and C. Laberge, B.M. Knoppers, & I. Panisset, "Multi-disciplinary Perceptions of

non-medical health-care professional, such as a genetics counsellor, nurse or technician.[23] Moreover, all physicians are ethically and legally obliged to remain abreast of advances and knowledge in their practice.[24] For, "[a]ll who hold themselves out to the public as engaging in genetic counselling services must possess sufficient knowledge, training, and skill to provide those services in a reasonable manner".[25] According to the Canadian College of Medical Geneticists, "[t]he health care professional assuming the counselling role should be knowledgeable about human genetics".[26] Furthermore, while not explicitly stated in the various codes and regulations governing physicians generally, the provision of genetics counselling is a necessary adjunct to any genetic testing.[27] There is also the obligation to refer

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Human Genetics in Canada: "Delphi" Results with Regards to the Practice of Medical Genetics" (1995) 3 Health Law Journal. 19-57 at 48.

23 With the introduction of formal procedures for the evaluation of training programs and individuals by the CCMG and the Royal College, high standards of competence have been established for individuals who hold themselves out as medical geneticists, J. Clarke, *supra*, note 20 at 144; see also *Crits* v. *Sylvester*, [1956] S.C.R. 991; *MacDonald* v. *York County Hospital*, (1973) 41 D.L.R. (3d) 321 (Ont. C.A.); finally, see *infra,* this ch., sec. 2(d).

24 Since genetics is a rapidly advancing and evolving area of medicine, it will be difficult for health care providers to retain the expertise needed to give patients proper disclosure of the risks, benefits and alternatives, see T. Caulfield, "The Allocation of Genetic Services: Economics, Expectations, Ethics and the Law" (1995) 3 Health Law Journal 213 at 225; See also *ter Neuzen* v. *Korn* (1995) S.C.C. (File No. 23773)where a doctor did not inform a patient of the risk of HIV infection through artificial insemination since there was no obstetric literature at the time indicating AI as a mode of HIV transmission, the S.C.C. held that the doctor was not negligent in this regard, that the behaviour of a gynaecologist/obstetrician must be assessed in light of the conduct of other ordinary specialists who possess a reasonable level of knowledge, competence and skill expected of such professionals in the field, in Canada, and that such conduct must be judged in light of the knowledge that ought to have reasonably been possessed at the time; finally see, *Maheux*, St-François 450-05-000364-80, J.E. 84-464 9 (Que. Sup. Ct.) where the Court held that the physician had not acted negligently by not offering an amniocentesis to the plaintiff since this procedure was not an accepted practice in 1977. The plaintiff had previously given birth to an affected child before consulting the physician during her second pregnancy. The second child was born affected.

25 S. Elias & G.J. Annas, *Reproductive Genetics and the Law* (Chicago: Year Book Medical Publishers,1987), at 36.

26 Canadian College of Medical Geneticists, "Policy Statement concerning DNA Banking and Molecular Genetic Diagnosis" (1991) 14:4 Clin Invest Med 363-365. See in particular Sharpe, *supra* , note 15.

27 D.C. Wertz & J.C. Fletcher, *Ethics and Human Genetics: A Cross Cultural Perspective* (Berlin, Springer-Verlag, 1989) [hereinafter *A Cross Cultural Perspective*]; *Proceed with Care*, vol. 2, *supra*, note 3 at 778ff; See *supra*, ch. 3, sec. 3. It is however an ethical obligation of the Canadian College of Medical Geneticists. See Canadian College of Medical Geneticists, "Professional and Ethical Guidelines" in F. Baylis & J. Downie, *Codes of Ethics* (Toronto: Department of Bioethics, Hospital for Sick Children, 1992) at 30. Canadian College of Medical Geneticists & Society of Obstetricians and Gynaecologists of Canada, "Canadian Guidelines for Prenatal Diagnosis of Genetic Disorders: An Update", (1993) 15:March Supp. Journal SOGC 15. Consider also that it is clear from the 1990 Ontario Conference on MSAFP Screening that obstetricians are reluctant to take on the task of counselling patients and interpreting results, particularly in the absence of additional financial compensation from the Ontario Health Insurance Plan (OHIP). Moreover, many practicing obstetricians may not be trained in the interpretation of the triple test, particularly since Canadian obstetricians are an aging specialty. Since many women will turn to their primary care provider for counselling, it is critical that they are appropriately trained, as outlined in private correspondence from Martha Forestell, Senior Consultant, Women's Health Bureau, Ontario Ministry of Health.

to a specialist when the physician lacks the necessary knowledge to perform or interpret genetic tests.[28]

The care and treatment of a patient need not be the best but only average, reasonable and prudent. The level of the standard of care is commensurate with the degree of risk and the particular task undertaken. As such, a higher standard of care is expected in the use of experimental protocols or innovative genetic therapies[29] and in tasks in which the margin of human and technical error can be reduced, such as in the labeling of DNA samples, the coding of patient files, the entry onto genetic registries, or the storage of DNA.[30] While the diagnostic laboratory has the responsibility of handling the sample, the "disposal, storage or continued use of DNA, once a diagnostic service has been provided, is a matter of local institutional policy".[31]

According to the 1991 policy statement of the Canadian College of Medical Geneticists, "[a]n error due to improper laboratory technique or due to improper estimation of disease likelihood, given the DNA results, is the responsibility of the laboratory". While, "[a]n error due to an incorrect statement of the genetic relationship of family members is the responsibility of the family or the health care professional submitting the samples. An error due to misdiagnosis of disease is also the responsibility of the health care professional."[32] As noted however, "[i]n practice, the division of responsibility will not always be clear-cut".[33]

The recognition by the Science Council of the pressing need for training, certification and accreditation on a national basis[34] and of the dangers of private laboratories performing

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28 Baylis, *ibid*; Picard & Robertson, *supra*, note 1; P. Lesage-Jarjoura, J. Lessard, S. Nootens, Eléments de responsabilité civile médicale (Québec: Les Editions Yvon Blais, 1995); A. Bernardot & R.P. Kouri, *La responsabilité civile médicale* (Sherbrooke: Revue de Droit Université de Sherbrooke, 1980).

29 *Halushka* v. *University of Saskatchewan*, (1965) 53 D.L.R. (2d) 436, 52W.W.R. 608 (Sask. C.A.); *Weiss* v. *Solomon* , [1991] R.J.Q. 731 (Que. S.C.); Medical Research Council of Canada, Guidelines on Research Involving Human Subjects (Ottawa: Minister of Supply and Services Canada,1987) [hereinafter Medical Research Council of Canada, 1987]; Medical Research Council of Canada, *Guidelines for Research on Somatic Cell Gene Therapy in Humans* (Ottawa: Minister of Supply and Services, 1990) [hereinafter Medical Research Council of Canada, 1990].

30 In Quebec, this heightened intensity of the duty of care could well be seen by the courts as entailing an obligation of result. An error then being presumed to be a fault (medical negligence).

31 Canadian College of Medical Geneticists, *supra,* note 26. See, also, *infra*, this ch., sec. 2(d).

32 *Ibid.,* at 365, statement 5.

33 S. Narod, D. Rosenblatt, E. Lamothe, "The Banking of DNA for the Prevention of Genetic Disease" (1991) 14:4 Clin Invest Med 359-362, at 361: "This is because several health care professionals may be involved with a family, and erroneous information provided by one physician may lead to a false prediction in an individual who is followed by another physician. [As to assignment of paternity]....[t]he doctor cannot be faulted if he is misled, especially if the family is unaware of the situation or is unwilling to raise the possibility."

34 Science Council of Canada, *supra*, note 19 at 55ff. Also reiterated in Canadian College of Medical Geneticists, *supra*, note 26 statements 6 & 7 at 365.

genetic tests has been underscored by the recent report of the Canadian Royal Commission on New Reproductive Technologies, which has recommended that "[a]ll genetics centres or other facilities providing prenatal diagnosis for genetic disorders and congenital anomalies be subject to compulsory licensing by the National Reproductive Technologies Commission".[35] Until these recommendations are implemented, the question of competence and delegation is legally hazardous for any physician involved in genetic testing, to say nothing of the dubitable quality of care that may be offered the patient.

(b) Duty to Inform and to Test

An ever-expanding duty to inform the patient of the nature, risks, consequences, and alternatives of genetic testing prior to obtaining consent has been recognized by the Canadian courts.[36] The Canadian College of Medical Geneticists maintains that "[t]he final responsibility, to be sure that the individual understands the information given, must rest with either a clinical geneticist, or a genetic associate or the requesting health care professional".[37] Most discussion to date has centered around the duty to inform upon finding non-paternity, but increasingly tests being performed for one disorder reveal the presence of another. An international survey found no consensus on this issue,[38] but the Science Council of Canada has proposed that, prior to testing, patients be warned of such possibilities and their wishes with respect to disclosure ascertained.[39] The area of reproductive and genetic decision-making is also one in which the duty to inform has attracted special scrutiny because of the larger policy issues and "quality of life" implications.

As noted by the Royal Commission, informed choice is a more appropriate approach than informed consent, since it requires not only explaining the nature, risks and consequences of a given course of action, but also the other alternatives and possible choices the patient may want to consider. This not only provides greater information and participation of the patient but also allows for time for reflection.[40] Implementing informed choice also requires a greater knowledge base on the part of the physician; in particular, of genetic

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35 *Proceed with Care*, vol. 2, *supra*, note 3, at 831 rec. 232.

36 *Hopp* v. *Lepp*, [1980] 2 S.C.R. 192, 13 C.C.L.T. 66, [1980] 4 W.W.R. 645, 32 N.R. 145, 22 A.R. 361 (S.C.C.); *Reible* v. Hughes, [1980] 2 S.C.R. 880, 14 C.C.L.T. 1, 114 D.L.R. (3d) 1, 14 L. Med. Q. 209, 33 N.R. 361. For an overview see Canadian Health Facilities Law Guide, *supra,* note 21, para. 1290.

37 *Supra* , note 26, at 365, statement 5.

38 D. Wertz, "Professional Perspectives: A Survey of Canadian Providers," (1995) 3 Health Law Journal. 59 at 73 (Table 1.C.1); see also, Wertz & Fletcher, *supra* , note 27 at 17ff.

39 Science Council of Canada, *supra*, note 19 at 73. See also B.M. Knoppers & C. Laberge, "DNA Sampling and Informed Consent" (1989) 140 CMAJ 1023-1028 [hereinafter "DNA Sampling"]. See also J.R. Botkin, "Fetal Privacy and Confidentiality", (1995) 25(5) Hastings Center Report 32-39 who argues that notions of fetal privacy and confidentiality may help define limits as to what test ought or ought not be offered and what parents may reasonably learn about the future of their child.

40 *Proceed with Care*, vol. 1, *supra*, note 3 at 93. See also *Proceed with Care*, vol. 2, *supra*, note 3 at 791 rec. 217.

indications and of referral options. Yet, with the exception of the diagnosis of "classical" single gene disorders, much of genetic information (common multifactorial conditions) is probabilistic risk information couched in language of susceptibility, risk factors, predictivity, and late or uncertain onset, making even informed choice between alternatives based on full knowledge and time for reflection difficult to attain. Further, the basic "non-directive" tenet of genetics counselling may be undermined (at the patients' request) while the eugenic underpinnings of counselling and testing may be disguised.[41] Will too much information be seen as too directive or too confusing in the absence of public education? Should non-directiveness prevail if this new at risk information is difficult to decipher and understand?

Recognition of the duty to perform genetic testing and informing with due care was interpreted by one American court as a deterrent to malpractice on the basis that imposition of the duty would foster the societal objective of accurate genetic counselling and testing.[42] As early as 1977, an American court found that a duty was owed to an unconceived child because the physician could reasonably have foreseen that the Rh negative woman who received a blood transfusion of Rh positive blood would one day have children who would be at risk for haemolytic disease.[43] Where a physician negligently performs a test or medical intervention, and causes harm to the foetus who is born affected and sues, such an action for prenatal injury is a simple extension of medical malpractice rules.[44] Similarly where a patient suffers harm and, for example, suffers emotional distress following an incorrect genetic

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41 R.F. Chadwick, "What Counts as Success in Genetic Counselling?" (1993) 19 Journal of Medical Ethics 43-46; See J. Clarke, *supra*, note 20 at 146 who notes that the principle of autonomy in genetic counselling takes the form of non-directive counselling, meaning that the counselling is restricted to the provision of information regarding diagnosis, natural history including the results of treatment, risks of occurrence, and options for prevention in terms that do not betray bias on the part of the counsellor, leaving the patient to make their own decision on what they perceive to be in their best interests; See D. Wertz, *supra,* note 38 at 64-65 where several vignettes in a survey question tested the limits of the non-directive approach (see Tables 1.D.1 and 1.D.2 at 75-76) the exception to non-directiveness being certain fetal conditions such as anencephaly, trisomy 13 and severe open spina bifida (see also Table 7.C.1) ; *Proceed with Care*, vol. 2, *supra*, note 3 at 778ff; Because of the potential impact of information derived from genetic testing (i.e. having to decide whether to terminate a pregnancy), it has been determined that the informed consent process in the genetic context should be as non-directive as possible. However, this may cause (causation) difficulties in as much as the patient does not receive any direct recommendations or advice. In this regard see *Arndt* v. *Smith* , (1995) 126 DLR (4th) 705 (B.C.C.A.); (1994) 21 C.C.L.T. (2d) 66 (B.C.S.C.) where the Court of Appeal overturned the decision of the trial judge who dismissed an action against a physician who failed to adequately disclose the risk of brain damage to a foetus exposed to chicken pox on the ground that the mother would have carried the foetus to term even if fully informed. Although the issue of liability was not in question, a new trial on causation and damages was ordered. See also A. Motulsky, "Predictive Genetic Diagnosis" (1994) 55 American Journal of Human Genetics 603 .

42 *Harberson* v. *Parke-Davis*, 98 Wa.2d 460,656 P.2d 483 (1983), later proceeding, 746 F.2d 517 (9th Cir. 1984). Note also that in a 1994 International Survey of Doctors, *The Medical Post* (Fall, 1994) at 55 noted that 69.5% of Canadian physicians believe the "(r)isk of malpractice suits forces physicians to order tests that may not be required". See also, E.W.Clayton, "The Dispersion of Genetic Technologies and the Law", (1995) 25(3) Hastings Center Report, Special Supplement, S13-S15 who notes that fear of wrongful birth claims (and other such litigation) is the most powerful force driving the dispersion of genetic tests.

43 *Renslow* v. *Mennonite Hospital*, 40 Ill.Arr.3d 234, N.E.2d 870 (1976), aff'd. 367 N.E.2d 1250 (1977).

44 *Cherry* v. *Borsman* (1992), 12 C.C.L.T. (2d) 137 (B.C.C.A.).

diagnosis followed by an unnecessary abortion of a healthy foetus, medical malpractice rules will also permit recovery.[45] Where, however, the plaintiff alleges that the physician's negligence in genetic testing or genetics counselling precluded an informed decision about whether to have a child, such that conception would have been avoided or the pregnancy terminated had they been properly advised or tested, the action of the parents is that of "wrongful birth" while the action of the child born with a genetic condition, is that of "wrongful life".[46] The claim of the parents is unique in that it does not arise from personal physical injury to themselves but rather from the negligent invasion upon their right to decide to avoid the conception or birth of a child with a congenital condition. The child's claim is also unique in that the allegation is that, but for the defendant physician's negligent testing or counselling of the parents, the child would not have been conceived or born. Both actions assert that the child would not have been conceived or would have been aborted if the testing or information had been properly applied.

Until recently, there were no reported Canadian cases of wrongful birth or wrongful life based on genetic malpractice. Malpractice cases in relation to suits for missed sterilization have been relied upon for relevant case law.[47] Whereas no damages were awarded for wrongful birth in the case of a missed sterilization followed by the birth of a healthy child,[48] damages were allowed in a 1986 Quebec case, in which an affected child was born following the vasectomy of a blind man with hereditary cataracts. The blind man had a vasectomy following the birth of an affected child by a first marriage. The routine post-operative sperm count was not performed and an affected child was born to his second wife. The parental claim for wrongful birth was allowed, although the child's wrongful life claim was not since, as regards the child, the defendant physician had not "caused" the genetic disorder in question. The court reasoned that, to award damages to the child would require measuring non-existence against existence with handicap. The child's claim alleged that damages should be awarded because he was born to experience the pain and suffering attributable to the

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45 *Martinez* v. *Long Island Jewish Hillside Medical Center*, 70 N.Y.2d 697, 518 N.Y.S.2d 955, 512 N.E.2d 538 (1987), on remd, 133 A.D.2d 264, 519 N.Y.S.2d 53 (1987).

46 B.M. Knoppers, "Modern Birth Technology and Human Rights" (1985) 33:1 American Journal of Comparative Law 1 [hereinafter "Modern Birth Technology"].

47 Distinguish with *Cherry* v. *Borsman*, *supra*, note 44: After a missed abortion and having failed to diagnose a continuing pregnancy, an infant was born with severe brain damage and physical abnormalities. The doctor was found negligent both in performing the abortion and in the post-operative care. He owed a duty to the adult plaintiff to perform the abortion with due care and a duty to the infant plaintiff not to injure her. The infants rights only arose when and because she was born alive at which point she had become an independent legal entity entitled to claim compensation for injuries suffered *in utero*. For comments on this case see Canadian Health Facilities Law Guide, *supra* , note 21 para. 15,243.

48 *Cataford* v. *Moreau*, [1978] C.S. 933 (Que. S.C.); *Doiron* v. *Orr*, (1978) 86 D.L.R. (3d) 719, 20 O.R. (2d) 71, 2 L. Med.Q. 237 (Ont. H.C.J.). However, see the case of *Cooke v. Suite* (1993) R.J.Q. 514, (1995) J.E. 95-2058 where the Court of Appeal upheld an action in damages against an obstetrician-gynaecologist for the care and maintenance of a healthy child after a failed sterilization. The court held that to deny damages would be to negate the direct fault of the doctor as well as the right of all couples to diligent and competent family planning assistance.

deformity, not for the fact of birth itself.[49] Now, however, in a landmark wrongful life case, the parents of a boy with severe birth defects are suing their family doctor arguing that the child should never have been born. They claim that, due to the physician's incorrect interpretation of the mother's MSAFP screen, they were not given the chance to decide whether to continue the pregnancy or prevent the birth of their severely disabled son through therapeutic abortion.[50]

American case law, while recognizing that there is no right to be born healthy, whole, and functional, has permitted a few wrongful life suits by the child where the injury was foreseeable, usually awarding costs above those of raising a non-disabled child, including costs for expenses incurred after the age of majority and, in some cases, damages for trauma.[51] Generally, genetics malpractice cases have been successful where the physician delayed in informing the parents of the results of genetic testing in time for an abortion,[52] where incorrect test information on the first child led the parents to conceive a second child with the same disorder,[53] where ultrasound tests were incorrectly interpreted,[54] where a physician failed to warn of the potential effects of medication on the foetus,[55] where negligent preconception counselling led to conception of an affected child,[56] where amniocentesis was not advised,[57] where rubella infection was not diagnosed in time,[58] where a positive family history of Down syndrome was not followed by genetics counselling[59] and, finally, where the

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49 *Engstrom* v. *Courteau* , (1986) C.S. 3048 (Que. S.C.). See also, *Joshi .(Guardian ad litem of)* v. *Woolley* (1995) 4 B.C.L.R. (3d) 208 (S.C.).

50 See D. Roberts, "Parents sue doctor over abnormal son: Claim boy shouldn't have been born" *Globe and Mail* (September 7, 1994) at A1.

51 On American wrongful birth and wrongful life cases, see generally, Family Law Series, *Handling Pregnancy and Birth Cases*, February 1993 & February 1994 supplement (Colorado Springs, CO: Shepard's/McGraw-Hill Inc., 1993, 1994) [hereinafter *Handling Pregnancy and Birth Cases*]. Note that at least four states have statutes that prohibit parents from bringing wrongful birth actions against health care practitioners and institutions. See Lori B. Andrews, "Torts and the Double Helix: Malpractice Liability for the Failure to Warn of Genetic Risks" (1992) 29(1) Houston Law Review 149 at 160 [hereinafter "Double Helix"]. See below text accompanying note 75.

52 *Garrison* v. *Medical Center of Deleware*, 581 A.2d 288 (De. 1989 opinion issued Octobre, 1990).

53 *Lloyd* v. *North Broward Hosp Dist*, 570 S.O.2d 984 (Fl.A. 1990); *Gallagher* v. *Duke Univ*, 852 F.2d 773 (4th Cir. 1988).

54 *Wilson* v. *Kuenzi*, 751 S.W.2d 741 (1988); *Keel* v. *Banach*, 624 So.2d 1022 (Ala. 1993).

55 *Harberson* v. *Parke-Davis*, 98 Wa.2d 460,656 P.2d 483 (1983), later proceeding, 746 F.2d 517 (9th Cir. 1984).

56 *Viccaro* v. *Milunsky*, 406 Ma. 777, 551 N.E.2d 8 (1990).

57 *Hayman* v. *Wilkerson*, 535 A.2d 880 (D.C.A. 1987).

58 *Smith* v. *Cote*, 128 N.H. 231, 513 A.2d 341 (1986).

59 *Phillips* v. *United States*, 566 F.Supp. 1 (D. S.C. 1981), later proceeding, 575 F.Supp. 1309 (D. S.C. 1983).

physician did not suggest testing in the case of advanced maternal age.[60] In spite of this case law, "since it is medically impossible to screen all patients for all known genetic abnormalities, the standard of care requires that specific screening tests be performed only on those patients who meet specific profile characteristics that warrant such tests".[61] However, as more efficient technologies become available and the manner of delivering genetic information changes, this standard is unlikely to remain unchanged.[62]

Interestingly, the standard of care required must often be evaluated on a case by case basis. In a case concerning the failure of a physician to suggest or provide Maternal Serum Alpha Fetoprotein testing and the subsequent birth of a child with Down Syndrome, the Court found insufficient causal connection between the lack of testing and the birth of the affected child and held that the physician did not breach the appropriate standard of care. Damages for loss of the chance to terminate the pregnancy was also refused.[63] Nevertheless, where a physician failed to disclose the availability of AFP (a-feto-protein) testing during pregnancy, the Court held that this constituted a breach of the standard of care.[64] In the case of cystic fibrosis, even though one in twenty-five Caucasians carry the gene for this disease, current tests are not sufficiently sensitive when used for carrier detection in the general population; as a result, such testing has been accepted as approved medical practice only for persons with a family history.[65]

Even where the tests are sufficiently sensitive, causation is often difficult to prove in post-conception negligence suits since the embryo-foetus is already affected *in utero*. The

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60 *Call* v. *Kezirian*, 135 Ca.A.3d 189, 185 Ca.R. 103 (1982).

61 M. Kaback cited in "Double Helix", *supra*, note 51 at 182.

62 D.N. Cooper & J. Schmidtke, "Molecular Genetic Approaches to the Analysis and Diagnosis of Human Inherited Disease: An Overview" (1992) 24 Annals of Medicine 29-42. See also E. W. Clayton, "Issues in State Newborn Screening Programs" (1992) 90:4 Pediatrics, 641 [hereinafter "State Newborn Screening Programs"].

63 *Simmons* v. *West Covina Medical Clinic*, 212 Ca.A. 695, 260 Ca.R. 772 (1989). See also, N.Press and C.H. Browner, "Risk, Autonomy, and Responsibility: Informed Consent for Prenatal Testing", (1995) 25(3) Hastings Center Report, Special Supplement S9-S12 who discuss MSAFP screening at length.

64 *Reed* v. *Campagnolo*, 630 A.2d. 1145 (Md. 1993).

65 See C.Caskey, *et al.*, "The American Society of Human Genetics Statement on Cystic Fibrosis" (1990) 46 Am. J. Hum. Genet. 393 who recommended that CF carrier testing be made available to individuals with a family history of CF (since the predictive power of a positive or negative test in the context of a family history is extremely high) and that screening of individuals or couples in the general population should not be offered until the rate of CF carrier detection improves. More recently, in its "Statement of the American Society of Human Genetics on Cystic Fibrosis Carrier Screening," (1992) 51 Am. J. Hum. Genet. 1443, the ASHG reasserted that carrier testing should be offered to individuals with a family history of CF or with a blood relative identified as a CF carrier. Although sensitivity of carrier testing for CF is improving, and the detection rate is approaching 90%, CF testing was not recommended for individuals within the general population. Of concern is the fact that there is little experience in the delivery of such complex information to large populations. As such, before carrier detection is offered to the general population, the effectiveness of educational materials, quality assurance and proficiency testing of screening laboratory tests, counseling issues and the beneficial and deleterious effects of screening must be addressed.

plaintiff must show that "but for" the negligence, the child would have been aborted. However, given that abortion is neither legally prohibited nor as politicized as in the United States, this proof might not be so difficult in Canada. Further, the fact that the physician did not "cause" the disorder, disease or condition has not prevented courts from indemnifying plaintiffs in malpractice suits based on other types of missed diagnoses.[66] What about those cases in which incorrect genetic testing leads to unnecessary sterilization, divorce, or recourse to reproductive technologies? Is the loss that of the chance to reproduce?

The Supreme Court of Canada has refused to accept loss of a chance as a ground for medical malpractice generally. In a case in which a physician failed to inform or counsel a patient diagnosed with cancer of the possible treatments available, the Supreme Court of Canada preferred to include the deprivation of the right to choose within the realm of general damages rather than as a type of damage in itself. The Court reasoned that "the loss of a chance analysis...is inappropriate, at least in cases where death or sickness has already occurred. In such cases, classical principles of causation suffice, and further, are essential in order for individual responsibility to attach."[67] By extrapolation, as regards genetics negligence claims, it may be argued that, whereas in post-conception negligence suits, (loss of a chance to abort for the parents, and not to have been born[68] for the child), the foetus in utero is already affected, in preconception genetic negligence claims (loss of a chance to avoid future harm), conception has not yet taken place and recourse to the loss of a chance approach may indeed be feasible.

At this time in Canada, then, physicians will be held to the standard of care of the average, reasonable practitioner following approved medical practice.[69] The 1993 CCMG/SOGC Guidelines provide *inter alia* that "fully" informed consent be obtained, that counselling be non-directive, and that prenatal diagnosis be offered to all women over thirty-five years of age or with a family history of genetic disease.[70] Likewise, according to the

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66 *Supra,* note 49 *Engstrom*, Case "Double Helix", *supra* , note 51 at 153; *Reed* v. *Campagnolo*, 630 A.2d. 1145 (Md. 1993): The court concluded that the parents did suffer harm in that they were essentially denied the opportunity to decide whether to terminate the pregnancy or to have a child with a severe birth defect (at 1150). As concerns causation, it was sufficient that the physicians' negligence was a "substantial factor" leading to the harm (at 1152).

67 *Laferrière* v. *Lawson* [1991] 1 S.C.R. 541 at 559.

68 Moreover, while at the moment in utero treatment is not usually attempted nor successful, when available for certain conditions, a missed diagnosis would also deprive the child of the opportunity to be treated before birth or immediately after based on the in utero diagnosis. For an innovative and novel interpretation of the *Laferrière* case and the application of loss of a chance to post-conception cases in Canada see Dubetz & Sherwin, (student paper, unpublished, University of Alberta,1993).

69 *Cherry* v. *Borsman*, *supra*, note 44.

70 *Supra*, note 26. Note however that triple screening has become standard practice in many areas thereby making prenatal diagnosis (PND) available to all pregnant women. As of July 1993, Ontario was the first province to implement a province wide coordinated triple maker genetic screening program. At least 50% of pregnant women in Ontario were screened during the first year of the program for risk of open neural tube defects and Down Syndrome. 50% participation is a strong indication that most women, if offered, will choose a PND screen. Research evaluating client understanding, anxiety and acceptability of the program

report of the Royal Commission, advanced maternal age, and known family genetic history are the current indicators for referrals for genetic testing.[71] Should every physician, however, who knows that a patient is planning to conceive or is already pregnant, ask whether there is a family history or inform her generally about available genetic testing? Should this same positive obligation to inquire or inform on the part of the physician apply to all patients who are members of identifiable ethnic or racial groups known to be at a higher risk for certain diseases, or only to patients (or their partners) who have already been identified as carriers?[72] What would be the extent of the obligation of a physician practicing in certain regions or populations closely identified with a known higher incidence of certain genetic conditions?[73] Suffice it to say that, like any other case of proven medical negligence, genetic malpractice suits and wrongful birth and wrongful life suits may be successful in Canada.[74] It should also be noted, however, that the untoward legal obligations placed on physicians, and this even in the post-natal period where the "information" communicated might well lead to pressure to abort, has prompted several American states to prohibit wrongful birth and wrongful life suits against physicians.[75]

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will be useful in determining whether participation PND is an informed reproductive choice for women or one imposed upon them by a society that tends to devalue the disabled. See Martha Forestell, *supra*, note 27.

71 See generally, *Proceed with Care*, vol. 2, *supra,* note 3, c. 26: "Prenatal Diagnosis for Congenital Anomalies and Genetic Disease".

72 See *supra,* ch. 2. See also the case of *Munro* v. *Regents of the University of California*, 263 Cal. Rptr. 878, (Ct. App. 1989) : The patient must be in a sufficiently high risk group for geneticists to offer a particular test (Tay-Sachs test among people of Ashkenazi Jewish background and a small French Canadian community.) In the *Munro* case the court decided that the defendant had no duty to disclose the risks and benefits of testing for Tay-Sachs because the Monros were not of Ashkenazi Jewish background and there was no reason to believe that their French Canadian relatives were from the small at-risk French Canadian community. For comments on this case, see "Double Helix", *supra* , note 51, at 162ff.

73 See *supra,* ch. 2 (e.g. in Eastern Quebec: myotonic dystrophy or in Alberta: Hutterites).

74 In *Proceed with Care*, vol. 2, *supra*, note 3, at 795 it was written: "(t)o summarize these two topics, wrongful birth suits brought by parents for reproductive risk malpractice are now widely accepted in U.S. jurisdictions. It is likely that such a suit would be allowed in Canada where avoidance of the risk could have been achieved by not conceiving the child or by aborting the fetus after PND. It is likely, however, that a wrongful life suit would be rejected in Canada." Note however the recent Manitoba case, *supra*, note 50 where the plaintiff's claim that due to the physician's incorrect interpretation of the mother's MSAFP screen, they were not given the chance to prevent the birth of their severely disabled son through abortion. In the absence of uniform statutory prohibitions of wrongful birth suits in Canada, this suit will set precedents in case law.

75 J.R. Botkin, M.J.Mehlman, "Wrongful Birth: Medical, Legal, and Philosophical Issues" (1994) 22:1 Journal of Law, Medicine & Ethics 21-28, at 22. See e.g. *Dansby* v. *Thomas Jefferson U.Hosp.*, 623 A.2d 816 (Pa.Super. 1993), where the court confirmed the constitutionality of a Pennsylvania statute prohibiting any cause of action for wrongful birth. See also E. W. Clayton, "Reproductive Genetic Testing: Regulatory and Liability Issues" (1993) 8(suppl 1) Fetal Diagn Ther 39-59, at 44-50; "While certain jurisdictions have recognized the validity of wrongful life actions, others have refused to grapple with the philosophical and ethical implications of such an allegation" in "Double Helix", *supra,* note 51 at 156. In 1987, 5 States prohibited children from bringing wrongful life suits against physicians. L.B. Andrews, *Medical Genetics: A Legal Frontier* (Chicago: American Bar Foundation, 1987)[hereinafter *Medical Genetics: A Legal Frontier*] at 148 and note 115 at 157.

(c) DUTY TO FOLLOW-UP[76]

The duty to follow-up a patient is an extension of the duty not to abandon a patient. Thus, even in cases in which the physician, for reasons of conscience, is morally opposed to an intervention such as abortion, there is a duty to refer.[77] The duty to follow-up also includes the duty following diagnosis or treatment to inform the patient of the results, to verify the efficiency of any intervention[78] and, in particular, to monitor the effects of any prescribed medication.

In the context of medical genetics where new mutations are being discovered at a rapid pace and where DNA is often banked, this duty to follow-up, unless circumscribed, is potentially without limit.[79] Indeed, there may be a duty to recontact and warn patients after learning of new more precise diagnostic tests that change the patients' genetic status and require another analysis of banked DNA, or, new information may simply change the significance of tests already performed. The fact that the physician or laboratory had only "a brief contact with the person providing the DNA or that much time has passed since the DNA was originally deposited does not provide a defence for not recontacting the patient".[80] This duty may be amplified where the state has certain controls on testing (for example, Army recruits in the United States, newborn screening,[81] and DNA criminal banks[82]) such that "[h]aving assumed to act, Government physicians [are] under a duty to act carefully, not

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76 See *infra,* ch. 9, for the potential duty to contact at risk relatives, spouses etc.

77 Picard, Robertson, *supra*, note 1; Bernardot & Kouri, *supra,* note 28; Canadian Medical Association, *Code of Ethics*, in Baylis, *supra* , note 27 at 34.

78 See *Engstrom* v. *Courteau, supra* , note 49; See *Handling Pregnancy and Birth Cases*, *supra*, note 51.

79 L.B. Andrews, "DNA Testing, Banking and Individual Rights" in B.M. Knoppers, C.M. Laberge, eds., *Genetic Screening from Newborns to DNA Typing* (Amsterdam: Elsevier Science Publishers B.V., 1990) 217-242 [hereinafter "DNA Testing"]; M..Z. Pelias, "Duty to Disclose in Medical Genetics: A Legal Perspective" (1991) 39 American Journal of Medical Genetics 347-354.

80 "DNA Testing", *ibid.,* at 225. See *Pittman Estate* v. *Bain* (1994), 112 D.L.R. (4th) 257 which held that once a physician is properly informed of new scientifically established tests that have become available, (s)he has a duty to "look-back", or re-do the tests, or rediagnose the results. Once the physician looks-back, the obligation to inform or recontact arises.

81 There is a duty to recontact female PKU patients at puberty who if successfully treated as children may not be aware of their status. For example the Quebec Network of Genetic Medicine keeps a register of all persons known to have PKU and notifies these individuals when they reach their 12th birthday in order to provide counselling. See L. Cartier *et al.*, "Prevention of Mental Retardation in Offspring of Hyperphenylalaninemic Mothers" (1982) 72:12 Am. J. Pub. Health 1386-1390; J.E. McEwan & P.R. Reilly, "Stored Guthrie Cards as DNA "Banks"" (1994) 55 Am. J. Hum. Genet. 196-200 [hereinafter "Stored Guthrie Cards"].

82 J.E. McEwan & P.R. Reilly, "A Review of State Legislation on DNA Forensic Data Banking" (1994) 54 Am. J. Hum. Genet. 941-958 [hereinafter "State Legislation on DNA Forensic Data Banking"].

merely in the conduct of the examination but also in subsequent communications to the examinee".[83]

The fulfillment of this duty implies an ongoing relationship with the patient or at the very least, knowledge of his or her whereabouts. While this is the case when the person tested is the patient, it is not so in many research protocols and family studies where family members participate by providing DNA but are not otherwise involved unless they so request. Considering the mobility of persons and the need to respect privacy (and where asked, the right not to know), extending the duty to follow-up to every person whose DNA is banked for other than treatment purposes would be virtually impossible.[84]

The CCMG Guidelines on DNA banking does not speak to this issue and limits itself to requiring the DNA depositor to provide the bank with consent "for such analyses that are in accordance with my wishes". It also provides specifically that the depositor entrust the bank to use samples for testing "to provide information that is valuable to the health and well-being of [the depositor]...[his] relatives and...[his] descendants".[85]

Physicians and institutions should make the conditions of banking and follow-up (or the lack thereof) clear at the time of participation.[86] However, this may well undermine informed choice, since the conditions would be imposed. While certain policies, such as non-commercialization, or conditions of banking, such as the type or length of storage, can be imposed, it has been suggested that, at the time of enrollment, the individual participant be asked to freely indicate whether or not he or she wishes to be recontacted and for what information (for example, new tests, new interpretation, possibility of treatment, or new research projects). Yet, it would be the participants' personal responsibility to notify the physician of any change of address or circumstances.[87] Where genetic registries are in place, and even more so where they are computerized, these reciprocal duties will have to be further refined.[88]

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83 "DNA Testing", *supra*, note 79, at 226.

84 See Sharpe, *supra,* note 15; "State Legislation on DNA Forensic Data Banking", *supra,* note 82.

85 Canadian College of Medical Geneticists, *supra*, note 26, at 364.

86 *Ibid.* See also "DNA Sampling", *supra*, note 39; Sharpe, *supra,* note 15.

87 B.M. Knoppers & C.M. Laberge, "DNA Sampling and Informed Consent - Revisited" (1991) 144:2 CMAJ 128-9; Comité de direction du RGHA, "Médecine génétique et recherche" (June 8, 1995) *Recherche en Santé* 30; B.M. Knoppers & C.M. Laberge, "Research and Stored Tissues: Persons as Sources, Samples as Persons?" (December 13, 1995) 274 (22)1806; E.W. Clayton et. al., "Informed Consent for Genetic Research on Stored Tissue Samples" (December 13, 1995) 274 (22) 1786.

88 C.M. Laberge & B.M. Knoppers, eds., *Registres et fichiers génétiques: enjeux scientifiques et normatifs*, (Montreal: ACFAS, 1992).

(d) Vicarious Liability

Physicians are responsible for those working under their supervision (for example, genetics counselors, nurses, and technicians) or in the case of medical geneticists, for the interpretation of genetic test results.[89] If a genetics counsellor is allowed to use independent judgment, it is likely that he or she would also be held to the same standard and be held liable.[90] The uncertain professional status of genetics counselors, their various levels of training,[91] and lack of accreditation, raise problems of competence similar to that of the general practitioner. While, as stated, physicians are responsible for those working under their supervision, the personal liability of counselors is not excluded.[92]

Like physicians, hospitals and private or provincial/regional laboratories are responsible for the activities and supervision of their employees and for defective equipment found within its genetics laboratories.[93] In addition to responsibility for the diagnoses themselves, conditions of storage, standards, duration, disposition and costs would fall under the responsibility of the hospital or institution.[94] They may also be held to have a general "corporate liability" for "the acts or omissions of physicians who hold staff privileges but who are not employees".[95] Would this include researchers who are not on staff, but who use hospital facilities and recruit patients for genetic testing protocols? The fact that, in most cases, the hospital administers the grants and approves the projects through its ethics committees may well be sufficient to bring these researchers under the umbrella of corporate liability.

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89 See generally on vicarious liability: Picard & Robertson, *supra* , note 1; Bernardot & Kouri, *supra*, note 28.

90 W.R. Kucera & J.N. Manson, "Allied Health Professionals: An Opportunity and a Challenge" (1980-81) 16 Forum 787, at 794.

91 At present there is only one Canadian training program at McGill University and one starting up at the University of British Columbia; see Science Council of Canada, *supra* , note 19, at 59.

92 Unless the counsellor is a member of another professional corporation, such as nursing, insurance will be problematic. See generally, on genetic counselling and responsibility M. Sidarous and E. Lamothe (1995) 3 Health Law Journal 153-174.

93 A successful wrongful birth and wrongful life suit was brought in *Curlender* v. *Bio-Science Lab.*, 165 Cal.Rptr. 477 (Ct App 1980) for negligently conducting preconception genetic tests.

94 See however Canadian College of Medical Geneticists, *supra,* note 26 at 364, which states in the sample consent form that "the trustee will endeavour to ensure the long-term preservation of the samples on deposit but can make no guarantees against the possibility of a catastrophic act leading to the destruction of the DNA bank."

95 Canadian Health Facilities Law Guide, *supra*, note 21 para. 1035. *Contra*, G. Robertson et al., "Legal Norms Relevant to the Practice of Human Genetics: A Background Paper" (1995) 3 Health Law Journal 187 at 194 who indicates that Canadian law views physicians (other than residents and interns) as independent contractors rather than employees of the hospital and as a result, their negligence does not render the hospital vicariously liable.

3. SPECIAL POPULATIONS

Most genetic diseases manifest themselves in childhood.[96] Certain participants in genetic testing and research however, such as newborns and children do not have the legal capacity to consent, or have limited capacity, such as adolescents (mature minors greater than approximately fourteen years of age), and adults with mental disorders. By law, these "incapable" populations attract specific forms of protection. While issues of competence, due care in testing and informing, follow-up, and responsibility for those acting under one's supervision remain, genetic testing and research with these populations raise specific concerns due to the need to protect, and one could also argue, due to the need to include.

(a) NEWBORNS

Programs for the genetic screening of newborns for metabolic diseases through the use of a heel prick blood test exist in North America, Europe, Australia, and Japan.[97] Screening programs search for at-risk individuals in a given population. Population newborn screening is for diseases that are treatable and usually not detected clinically before the effects are irreversible.[98] The accepted criteria for inclusion of a disease in a universal newborn screening program are: (1) the disease will result in severe morbidity (mental and physical) and/or mortality if it is not diagnosed in the neonatal period; (2) clinical screening by simple physical examination is not effective and will not identify the disease; (3) an effective treatment is available; (4) there is a significantly improved prognosis with early treatment; (5) the disease has a relatively high incidence (greater than one in 15,000 infants); and (6) there is a simple, rapid, reliable, inexpensive screening test.[99] In spite of this general acceptance, newborn screening programs have attracted attention recently with regard to the issues of consent and DNA banking.[100]

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96 Science Council of Canada, *supra*, note 19.

97 S.J. Fox and D. Young, "International Protection of the Children's Right to Health: The Medical Screening of Newborns" (1991) 11 Boston College Third World Law Journal 1-43; World Health Organisation, Division of Noncommunicable Diseases and Health Technology, Hereditary Disease Programme, *Guidelines on the Prevention and Control of Phenylketonuria (PKU)*, (Geneva: WHO,1990); Illinois Department of Public Health, *An Overview of Newborn Screening Programs in the United States and Canada* (Illinois: 1993); Public Health Branch, Ministry of Health, Ontario, *Revised Guidelines for Newborn Screening for Phenylketonuria & Hypothyroidism*, (Ontario: 1991).

98 B.M. Knoppers, C.M. Laberge, eds., *Genetic Screening from Newborns to DNA Typing* (Amsterdam: Elsevier Science Publishers B.V., 1990), [hereinafter *Genetic Screening*]. The most common diseases tested for are: hyperphenylalaninemias and congenital hypothyroidism. But many provinces, states and countries add other diseases depending on the criteria of prevalence, treatability and non-detection before the effects are irreversible.

99 *Ibid.*; National Academy of Sciences, Committee for the Study of Inborn Errors of Metabolism, *Genetic Screening: Programs, Principles and Research* (Washington, D.C.: National Academy of Sciences, 1975); See also Nuffield Council on Bioethics, *supra*, note 10 at 93, rec. 10.1.

100 "State Newborn Screening Programs", *supra*, note 62.

Indeed, in contrast to a recent United States Institute of Medicine report[101] suggesting the mandatory "offering" of newborn screening and the receipt of informed consent from the parents,[102] an earlier international survey on ethics and genetics[103] (like other national commissions)[104] considered this to be the only form of genetic testing for which no explicit parental consent was necessary. It held that newborn screening for treatable, metabolic diseases should be mandatory. Whether one presumes the consent of the parents, uses the informed refusal approach,[105] or mandates screening by law,[106] the rationale for mandatory screening is that it is in the child's interest to be "found" through screening. It is also argued that the right of the child to enjoy the best state of health possible,[107] the obligations of parents under criminal[108] and civil law[109] and those of the youth protection authorities[110] are such that screening is mandated.[111] Indeed, since the false-positive rate in mass screening is higher, the necessary individual confirmatory diagnosis would still be subject to the usual rules of parental authorization and possibly contestation of any parental refusal by child protection authorities. Furthermore, the seeking out of a child at risk where clinical diagnosis

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101 Committee on Assessing Genetic Risks, *supra*, note 13 at 100.

102 *Ibid.*

103 See *A Cross Cultural Perspective*, *supra,* note 27; D.C. Wertz & J.C. Fletcher, "International Perspectives on Voluntary versus Mandatory Screening and Third Party Access to Test Results" in *Genetic Screening*, *supra*, note 98, at 243.

104 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Screening and Counseling for Genetic Conditions* (Washington, D.C.: U.S. Government Printing Office, 1983); See also Sub-Committee of the National Council of Bioethics and Human Research, "Report of the Working Group on Research with Children with Genetic Disorders" (1993) 4:1 Communiqué 33, at 33.

105 "This approach provides information to the parents and will proceed with screening unless the parent(s) dispute the screening." B.M. Knoppers, "Newborn Screening and Informed Consent" in J.P. Farriaux & J.L. Dhondt, eds., *New Horizons in Neonatal Screening* (Amsterdam: Exerpta Medica, 1994) 15-24, at note 6 [hereinafter "Newborn Screening"].

106 For Canada and the U.S.A. see Illinois Department of Public Health, *supra* , note 97. See also World Health Organisation, *supra*, note 97, at 12: "It is perhaps easier to approach newborn screening for PKU through a legislative mandate in the sense that such mandates usually carry political and financial support... Legislation should require universal screening in order to be most effective since experience in systems where choices are allowed have sometimes led to abuses of the intent of the programme."

107 *Convention on the Rights of the Child*, (adopted Nov. 10, 1989), U.N. Doc. A/44/736 (1989), art. 24.

108 Article 215(1)(a) Criminal Code.

109 Articles 599ff Civil Code of Quebec.

110 *Child and Family Services Act*, R.S.O. 1990, c. C.11.

111 "Newborn Screening", *supra* , note 105.

would be too late and where treatment is available could also be considered an exercise of the *parens patriae* powers and duties of the state to protect the incapable.[112]

The general trend towards a greater respect for patient autonomy has, as we have seen, expanded the obligations of physicians. At the same time, newborn screening programs for treatable genetic diseases have been used, for example, for anonymous surveillance studies for HIV prevalence,[113] and surprisingly, for cystic fibrosis[114] and Duchenne's muscular dystrophy thereby attracting greater scrutiny. How then to ensure physician and parental responsibility and at the same time respect the rights of a vulnerable population such as newborns to be screened but not made the subjects of unwarranted testing or research?

Rather than the current practice of requesting or presuming permission immediately after birth, some authors have suggested that specific written parental consent be obtained prior to delivery at the time of admission or after the birth.[115] This could create insurmountable administrative problems for the physician and for the screening program unless the consent was a typical *pro forma* general clause like others signed upon admission. In the absence of such a general consent form (and considering the fact that most confinements are less than forty-eight hours), would the heel prick screening test be

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112 *E(Mrs.)* v. *Eve*, [1986] 2 S.C.R. 388, 31 D.L.R. (4th) 1, 71 N.R. 1, 13 C.P.C. (2d) 6, 61 Nfld & P.E.I.R. 273, 185 A.P.R. 273.

113 See, for example, C. Hankins, "Research or Surveillance: Anonymous Seroprevalence Studies - Ethical and Epidemiological Considerations in Public Health Planning" in *Genetic Screening*, *supra* , note 98, 87 at 90ff; C.A. Hankins *et al.*, "Human Immunodeficiency Virus Infection among Quebec Women Delivering Live Infants" (1990) 143 Can. Med. Ass. J. 885-893. See also, N. Touchette, "Agency Halts HIV Survey in Dispute over Newborn Data", (1995) 375 Nature 169 where the CDC was said to have suspended a $10.5 million surveillance study to track HIV infection in women in order to avoid being forced by Congress to collect full details of HIV exposure in newborn children.

114 N.A. Holtzman, "What Drives Neonatal Screening Programs?" (1991)325 New Eng. J .Med. 802-804 who believes that even in cases where there is familial risk for the disease, early detection has no value and may even cause the family significant psychological stress prior to the time when the individual might become symptomatic; S.Raskin, *et al.* , "DNA Analysis of Cystic Fibrosis in Brazil by Direct PCR Amplification from Guthrie Cards" (1993) 46 Am. J. Med. Genet. 665-669; "Stored Guthrie Cards", *supra*, note 81. Note that the state of Wisconsin established an experimental newborn screening program in 1985 however, the first five years of the program provided no evidence that presymptomatic detection had any clinical benefit, and given a number of psychological and ethical issues, researchers concluded that it was premature to offer population wide screening until the benefits and risks were clearly determined: P.M. Farrell and E. H. Mischler, "Newborn Screening for Cystic Fibrosis" (1992) 39 Advances in Pediatrics at 66 . However, see M.E. Balnaves, L. Bonacquisto, et. al., "The Impact of Newborn Screening on Cystic Fibrosis Testing in Victoria, Australia"(1995) 32 J. Med. Genet. 537-542 who found that newborn screening dramatically reduced the time of diagnosis of CF to approximately six weeks or less in the majority of cases. For the affected child, this means prompt treatment of symptoms although the effect of long term prognosis was considered unclear. See also, B.S. Wilfond, "Screening Policy for Cystic Fibrosis: The Role of Evidence", (1995) 25(3) Hastings Center Report, Special Supplement, S21-S23.

115 "State Newborn Screening Programs", *supra*, note 62, at 644; *Medical Genetics: A Legal Frontier*, *supra*, note 75; N.A. Holtzman *et al.*, "Effect of Informed Consent on Mothers' Knowledge of Newborn Screening" (1983) 72:6 Pediatrics 807; R. Faden *et al.*, "A Survey to Evaluate Parental Consent As Policy for Neonatal Screening" (1982) 72:12 AJPH 1347.

considered an assault?[116] What would be the potential liability of the hospital or physician when, due to the absence of a written consent, no test was performed? Moreover, what would be the legal and ethical validity of a general clause inserted in an admissions form signed by a woman in labor with regard to consent to screening or pilot projects on newborns? Others have suggested that, in addition to the usual information now given to parents at birth, information be given during the pregnancy so that they have time for reflection and questions. If no questions are asked or no refusal forthcoming, then consent can be presumed.[117]

Finally, since it is the newborn who is the patient, it could be asked whether the physicians' duty to the newborn is to screen for metabolic diseases as a matter of normal routine pediatric care (which for adults would include, for example, blood typing prior to surgery).[118] Under this approach, the general consent signed upon admission, which covers all routine hospital procedures and practices, would be sufficient. If so, only confirmatory testing or other testing done or the use of the blood spots for other diagnostic purposes, pilot projects or research would require a specific parental consent. It remains for each jurisdiction to decide which treatable, metabolic disease tests would be considered routine.[119]

This was the issue in a Saskatchewan Court of Appeal case in which a child was not screened at birth for maple syrup urine disease (MSUD—a rare disease that, if not diagnosed and treated promptly, leads to mental retardation and cerebral palsy). The parents sued the physicians for negligence, but failed, since testing for the disease was not routine (though the issues of which physician should have identified it clinically, causation, damages and loss of a chance were sufficient to order a new trial). The court remarked on "the need for a universal screening programme for metabolic diseases including MSUD in newborn babies... [A]ll were in agreement that such a catastrophe would not have occurred with such a programme in operation".[120]

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116 Technically, yes according to Medical Research Council of Canada, 1987, *supra,* note 29 at 29; See also C. Bernard & B.M. Knoppers, "Legal Aspects of Research Involving Children in Canada" in B.M. Knoppers, ed., *Canadian Child Health Law* (Toronto: Thompson Educational Publishing, 1992) 259 at 276.

117 A truly "informed" informed-refusal approach! See "Newborn Screening", *supra* , note 105, at 117; See also R.R. Faden, N.A. Holtzman & A.J. Chwalow, "Parental Rights, Child Welfare, and Public Health: The Case of PKU Screening" (1982) 72: Am. J. Pub. Health 1396-1400 at 1398.

118 This is the case in Quebec where a by-law of the *Health Services and Social Services Act* delegates to the Corporation of Physicians and Surgeons the power to decide which tests should be undertaken routinely in health establishments. According to the *Canadian Charter of Rights and Freedoms*, Part 1 of the *Constitution Act, 1982*, Schedule B of the *Canada Act 1982* (U.K.), 1982, c. 11, by-laws passed pursuant to legislation have force of law.

119 Ontario, which currently screens for PKU and CH, is considering adding congenital adrenal hyperplasia. See Ministry of Health, *Revised Guidelines for Newborn Screening , supra,* note 97.

120 *Quintal* v. *Datta* [1988] S.J. No 771, File no. 9306.

The other area in which different and new areas of genetic malpractice are immediately evident, is that of DNA banking.[121] At present, most programs keep the blood spots for a limited time (for example, one year in Quebec), for confirmatory purposes and for approved research. Only for those infants who are found to be affected are blood spots part of the medical record so as to ensure follow-up. The sheer number would make storage of spots of all newborns prohibitive and, in the absence of parental consent (and maybe one day, ratification by the minor?[122]), legally onerous, in that the problems of the duty to further test or to follow-up could arise. Moreover, while these banks are potentially a rich resource for epidemiological studies, diagnoses of other family members, or identification of missing children, they could also be misused by third parties such as insurers, employers, and criminal investigators.[123] Physicians would have insurmountable difficulties in maintaining confidentiality and would have to seek parental consent and later that of the minor for any uses.[124]

(b) CHILDREN

Once past the narrow time frame of newborn testing for treatable metabolic disorders, pediatric involvement in the clinical diagnosis of genetic conditions in children is mostly for developmental disorders, cardiac malformations, motor disabilities, respiratory disorders, and physical growth disorders—the diseases of childhood.[125] It is estimated that up to half of the admissions to pediatric hospitals are for genetic diseases.[126] Indeed, it is usually the clinical diagnosis of a child that brings to light the genetic status of the entire family. The genetic testing of children has expanded to include testing for symptomatic conditions or presymptomatic testing, testing for the benefit of others, testing for research purposes, or, for

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121 Particularly in view of the case *Pittman Estate* v. *Bain*, *supra*, note 80 where both the blood bank and the hospital were held to have acted negligently in failing to adequately implement a "lookback" program, designed to identify blood donors who were HIV-positive, and in turn identify the recipients who were transfused with the tainted blood. See Canadian Health Facilities Law Guide, *supra,* note 21 at para. 15, 263.

122 Sub-Committee of the National Council of Bioethics and Human Research, *supra* , note 104 at 34; see also D. Wertz, supra, note 38 at 92 where the majority of survey respondents thought that newborn blood spots should be kept indefinitely and that children should have access to their bloodspots at age 18 (Table 3.B.4 at 98).

123 See "Stored Guthrie Cards", *supra*, note 81. See, also, *infra,* chs. 5 and 6.

124 G.C. Cunningham, "Balancing the Individual's Rights to Privacy Against the Need for Information to Protect and Advance Public Health " in *Genetic Screening*, *supra*, note 98 at 205.

125 B. Childs, C. Scriver. "Age at Onset and Causes of Disease" (1986) 29 Perspectives in Biology and Medicine, 437-460.

126 Science Council of Canada, *supra*, note 19 at 23. Canadian Institute of Child Health, "Children and Youth with Disabilities in Canada" (1993) 15:4 Child Health 1. See also *The Health of Canada's Children: A CICH Profile,* 2nd edition, (Ottawa, 1995).

somatic cell therapy protocols, testing for predisposition or susceptibility to predict a child's future risk, and testing for carrier status at an age when the child cannot procreate.[127]

Presymptomatic and susceptibility testing of children or testing for carrier status raises special concern given that early testing may not (yet) necessarily lead to clearly beneficial or effective treatment. Tests that predict the likelihood of predisposition to certain cancers,[128] as well as presymptomatic tests for genetic disorders that ordinarily first appear in adulthood, such as Huntington disease, polycystic kidney disease, and Li-Fraumeni syndrome, are currently available. There is, however, some controversy regarding the use of these presymptomatic tests for children.[129] While many have characterized the initiative to market such tests as alarming since such genetic testing is not only still in the research phase, but could cause children serious psychological consequences,[130] others argue that geneticists have a legal and moral duty to advise parents about presymptomatic testing procedures and this for even late onset diseases.[131]

Notwithstanding these different schools of thought, many ethicists and professional genetics societies agree that genetic testing for children is appropriate only when a clear and timely benefit (treatment or prevention) to the child exists.[132] The dilemma that remains

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127 D. Wertz, J.H. Fanos and P.R. Reilly, "Genetic Testing for Children and Adolescents: Who Decides?" (1994) 272 JAMA 875-880; (hereinafter Wertz et al.,); N. Fost, "Genetic Diagnosis and Treatment: Ethical Considerations" (1993) 147 American Journal of Diseases of Children 1190-95.

128 See G. Kolata, "Tests to Assess Risks for Cancer Raising Questions" *New York Times*, March 27, 1995 at A1. Tests are now available for predisposition to breast cancer, colon cancer, melanoma, and thyroid cancer.

129 Harper & Clarke, "Should We Test Children For 'Adult' Genetic Diseases?"(1990) 335:8699 Lancet 1205-1206; F.N. Sharpe, "Presymptomatic Testing for Huntington Disease: Is There a Duty to Test Those Under the Age of Eighteen Years?" (1993) 46 American Journal of Medical Genetics 250-53 (hereinafter Sharpe, Presymptomatic Testing); Clinical Genetics Society, "The Genetic Testing of Children: Report of a Working Party of the Clinical Genetics Society", (1994) Birmingham Maternity Hospital, 32pp; *Proceed with Care, supra,* note 3. See also American Society of Human Genetics and American College of Medical Genetics, "Points to Consider: Ethical, Legal, and Psychosocial Implications of Genetic Testing in Children and Adolescents (1995) 57 Am. J. Hum. Genet. 1233-1241 (hereinafter ASHG-ACMG Report).

130 Wertz et al., *supra*, note 127. See also, G. Kolata, "Should Children be Told if Genes Predict Illness?" *New York Times*, September 26, 1994 at A1 & A14.

131 Sharpe, *supra,* note 129.

132 ASHG-ACMG Report, *supra*, note 129; A. Clarke, Working Party of the Clinical Genetics Society, "The Genetic Testing of Children (1994) 31 Journal of Medical Genetics 785; Institute of Medicine, L.B. Andrews et al.., eds., *Assessing Genetic Risks, supra,* note 13 at 10; Nuffield Council on Bioethics, *supra*, note 10, states at 4.25: "Genetic screening of children which is not of immediate benefit to them should normally be deferred until they can give valid consent. An exception may be where testing of the child is essential for the diagnosis of a family member, though it may be difficult to argue that such testing is always undertaken to promote the interests of the child. The genetic testing of children for late onset/adult diseases raises particularly difficult issues of informed consent and is likely to become increasingly important as a growing number of genes which predispose to disease in later life are being discovered... particular caution is needed when any wider screening of children for later onset genetic disorders is to be considered."; Council of Europe R (92)3, *supra*, note 9 at princ. 5, recommends that testing of minors "for diagnostic purposes should

concerns the debate over what constitutes a clear and timely benefit and who would benefit from the information.

Concerns about testing children for predictive purposes rest largely on the need to balance potential psychological harms with possible benefits. Testing may well restrict a child's future, affect the socialization process, cause risk of stigmatization, loss of self esteem, and discrimination.[133] A 1991 affirmative recommendation for the predictive testing of children from Li-Fraumeni syndrome families by the National Cancer Institute and the National Center for Human Genome Research with the goal of reducing cancer morbidity and mortality was based on the unsupported optimism that increased knowledge of disease status will be a benefit to the child.[134] Studies indicate, however, that since the majority of cancers seen in Li-Fraumeni syndrome are incurable, increased cancer surveillance and early disease treatment are of no benefit. Further, there is no evidence linking knowledge of the existence of a mutant gene with any benefit to the child.[135] Given the potential psychological harms that may arise from identifying a child with a genetic predisposition, the International Huntington's Disease Association and the World Federation of Neurology have issued policy statements recommending that children not be tested for Huntington's disease.[136] Likewise, the National Kidney Foundation has recommended that children not be tested for adult polycystic kidney disease except in specific clinical circumstances in which preventive measures for stroke are applicable.[137]

In their joint 1995 statement, the ASHG and ACMG recommended that "timely medical benefit to the child should be the primary justification for genetic testing in children and adolescents," and that if medical benefits "are uncertain" or will not accrue until a later time, genetic testing should generally be deferred.[138] There is little difficulty in cases in which

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be permitted only when it is necessary for their own health or of the information is imperatively needed to diagnose the existence of a genetic disease in family members."

133 Wertz et al., *supra*, note 127, at 876.

134 Fost, *supra,* note 127.

135 *Ibid.*

136 Wertz et. al., *supra,* note 127, at 875, citing L. Went,"Ethical Issues Policy Statement on Huntington's Disease Molecular Genetics Predictive Test" (1990) 27 J. Med. Genet. 34-38; D.E. Hoffmann & E. Wulfsberg, "Testing Children for Genetic Predispositions: Is it in Their Best Interests?" (1995) 23(4) Journal of Law, Medicine & Ethics 331-44 at 334. See also Sharpe, *supra*, note 131; M. Bloch & M..A. Hayden, "Opinion: Predictive Testing for Huntington Disease in Childhood: Challenges and Implications", (1989) 46 Am. J. Hum. Genet. 1-4; M. Huggins et al., "Predictive Testing for Huntington Disease in Canada: Adverse Effects and Unexpected Results in Those Receiving a Decreased Risk" (1992) 42 Am. J. Med. Genet. 508-515; J. Clarke, *supra,* note 20 at 145 who notes that presymtomatic testing of minors for the presence of the Huntington disease gene is generally regarded as inappropriate.

137 Wertz et al., *supra*, note 127, at 876., citing Gabow et al., "Gene Testing in Autosomal Dominant adult Polycystic Kidney Disease: Results of a National Kidney Foundation Workshop" (1989) 13 Am. J. Kidney Dis. 85-87; Hoffmann & Wulfsberg, *ibid.*

138 ASHG-ACMG Report, *supra*, note 129, at 1233; Wertz et. al.,, *supra,* note 127, at 879 who notes that testing should be offered at the earliest stage when health benefits accrue, but need not be offered before this time.

testing offers immediate medical benefit for the child, either in terms of prevention or treatment. In fact, it may well be argued that testing is warranted, for example, in the case of familial hypercholesterolemia, where diet and medication reduce cholesterol levels.[139] Moreover, where treatment or prevention of expression of the disease is available, some would argue that there is a positive duty to test and treat the child, thereby limiting traditional parental authority.[140] The difficulty arises in cases in which there is no clear medical benefit and in which the parents or child request testing regardless of available preventive intervention or treatment and irrespective of sexual activity.

Parents who wish to have their child tested genetically will have to weigh the possible benefits of the test with the potential impact on the child's life. Although parents are usually in the best position to make such a decision about their children, they often do not realize that "planning for the future" (the most frequently given reason for testing) may "(restrict) the future".[141] The psychological and emotional value of the test information is likely to be different for parents than for the child. Notwithstanding these concerns, parents may persistently want their child to be tested. Some have argued that to deny parents access to genetic tests for their children is medical paternalism.[142] Others believe that, where such parental requests serve no useful medical purpose, such paternalism is justified.[143] A good compromise may be to present familial requests for testing to an ethics committee for consideration. Although parents are very seldom denied the right to make medical decisions for their children (except in cases involving neglect or parental abuse), such a review may be warranted, given that physicians are not required to provide testing without direct medical benefit simply because it may allay parental anxieties.[144]

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139 ASHG-ACMG Report, *ibid.*, at 1234; Wertz et al., *ibid.*, at 875.

140 "Newborn Screening", *supra*, note 105. This argument is particularly persuasive in human genetics where childhood diseases are usually severe, lethal, debilitating, irreversible and of early onset. See Sharpe, *supra*, note 131 who argues that physicians may have a positive legal duty to disclose the availability of genetic tests to the parents of presymptomatic (genetically predisposed yet still healthy) children.

141 Wertz et. al ., *ibid.*, at 878; Hoffmann & Wulfsberg, *supra,* note 136, at 333.

142 M.Z. Pelias, supra, note 79, at 350.

143 J.F. Childress, *Who Should Decide? Paternalism in Health Care (New York, N.Y: Oxford University Press Inc 1982);* See also G.J. Annas, L.H. Glantz & P.A. Roche, *The Genetic Privacy Act and Commentary* (Boston: Boston University School of Public Health, 1995) which limits some of the discretion parents have to consent to genetic testing by prohibiting DNA analysis of children under the age of sixteen for any condition that will not be manifested until after the child reaches adulthood, unless some effective measure can be taken before that time to prevent or ameliorate the condition. As a result, parents may consent to surgery for their children but not to genetic testing where there is no countervailing benefit.

144 D. Wertz, *supra*, note 38, at 78-79 where most survey respondents indicated that they would refuse parental requests to test asypmtomatic children or adolescents for disorders that occur later in life in the absence of medical benefit to the child. Benefit to the child was determined in terms of prevention or treatment: prevention may be possible and effective for familial cancers or hypercholesterolemia but there is no prevention or treatment for Huntington or Alzheimer disease (see Table 2.C.1 at 87); J. Clarke, *supra,* note 20, at 145 who reiterates that testing presymptomatic minors is inappropriate unless the results of the testing have a direct influence on the treatment of the child themselves. Note also that general medical decision

Thus, notwithstanding that parents may best know what is in their child's interest, physicians are under no obligation to provide genetic testing that *they* believe is not in the child's best interests.[145] Of particular concern is whether physicians must or should disclose the availability of genetic tests to parents of healthy children. Issues of potential liability for failure to inform parents about such tests arise. Some argue that physicians have a legal duty to disclose the availability of these tests.[146] Others argue that liability should attach only when a beneficial intervention exists and failure to test or to test in a timely manner would result in harm to the child.[147] Therefore, for genetic disease for which there is no effective preventive intervention or treatment, a physician would have no legal duty and should not fear liability for failure to inform parents of a genetic test, and this, irrespective of whether or not there is a family history or probable cause for believing the child has a genetic predisposition.[148]

Accordingly, these proponents recommend that the appropriate authorities issue a statement of non-disclosure where no available preventive intervention or treatment would benefit the child; where family histories do exist, guidelines as to when disclosure of a predictive test is appropriate should be put in place. Distinctions regarding disclosure can be made however, between cases in which there is and is not a family history of disease. Testing children with no family history of disease could be considered tantamount to a unwarranted fishing expedition. When there is a family history of disease, the ASGH-ACMG report recommends that the decision to test be made by a physician in discussion with the child and the child's parents, and thus disclosure, in such circumstances, is warranted.[149]

Testing children for genetic predisposition, therefore, raises new issues in terms of informed consent. With respect to children's participation in decisions to be tested, several authorities generally maintain that genetic testing that confers no benefits on the child should be deferred until adulthood.[150] However, these authorities concede that presymptomatic testing may benefit some minors by enabling them to make plans for the future. Under these circumstances, it is argued that the minor should actually initiate the request for testing and that "[t]horough counseling of both the minor and family (including siblings) should precede testing, to assess the inner strength of all concerned".[151] They further argue that no ethical

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making differs from decision making involving genetic testing in that in the former instance it is usually the physician recommending a course of action that the parents refuse as compared to the latter instance where the parents want a procedure that the physician refuses to perform.

145 See ASHG-ACMG report, *supra,* note 129; Hoffmann & Wulfsberg, *supra*, note 136.

146 See Pelias, *supra*, note 79, and Sharpe, Presymptomatic Testing, *supra*, note 131.

147 Hoffmann & Wulfsberg, *supra*, note 136, at 334.

148 *Ibid.,* at 335.

149 ASHG-ACMG Report, *supra*, note 129.

150 ASHG-ACMG Report, *ibid.;* Wertz et. al, *supra,* note 127.

151 Wertz et. al ., *ibid.,* at 879.

justification ordinarily exists for testing before the age of eleven or twelve years, absent proven medical benefits or prevention.

The issue of consent was also addressed in the research context. In 1978 the Medical Research Council of Canada[152] recommended that research involving children unable to consent be limited to research with a potential benefit for the particular child.[153] In 1992, however, the National Council on Bioethics, in a study on research involving children, criticized the limits of this 'direct benefit' approach. The exclusion of children from research in the absence of proven benefit to them was seen as running contrary to the ethical principle of non-maleficence (do no harm/prevent harm).[154] Some diseases affect only children and benefit to that class alone was seen as sufficient, provided other procedural protections were in place. This would be particularly true for genetic diseases of children.

Specifically with respect to research, a 1990 Medical Research Council sub-Committee recognized that "restricting research on gene therapy to those subjects able to consent will exclude the most severely affected patients in whom there is early onset of the disease and rapid deterioration"[155] and permitted somatic cell therapy trials under certain conditions.[156] This prepared the way for the inclusion of children in trials of somatic cell therapy. Interestingly, the duty of follow-up by the physician became the duty of participating children to be followed.[157] Moreover, the report mentioned that physicians had a specific duty

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152 Medical Research Council, *Ethics in Human Experimentation, Report No. 6* (Ottawa: Minister of Supply and Services Canada, 1978). See also C. Bernard & B.M. Knoppers, *supra,* note 116.

153 See e.g. *E(Mrs.)* v. *Eve*, *supra*, note 112 where the Supreme Court of Canada applied the best interest criteria in the case of an incompetent adult. "The Court was asked to authorize sterilization of a mentally disabled woman for non-therapeutic reasons. ...[T]he authorization was not granted because the Court refused to allow an irreversible operation which it considered as non-therapeutic and which would infringe one of the fundamental rights of a human being, the right to procreate. ... At first glance a restrictive interpretation of this decision could effectively ban non-therapeutic research involving children. But such an interpretation does not take into account the particular facts of the case nor the varying nature of proposed non-therapeutic intervention, degree of risk and the level of harm which could be found acceptable in other situations." C. Bernard & B.M. Knoppers, *supra* , note 116 at 306. Hence, one cannot consider illegal all non-therapeutic research with those incompetent to consent. See also Medical Research Council, 1987, *supra,* note 29 at 29; Medical Research Council, 1990, *supra,* note 29, at 25-27.

154 National Council on Bioethics on Human Research, *Report on Research Involving Children* (1992). In Sub-Committee of the National Council of Bioethics and Human Research, *supra*, note 104, guidelines for the involvement of children in research were delineated.

155 Medical Research Council of Canada, 1990, *supra*, note 29, at 25.

156 *Ibid.*, at 12: "It is our view that, for the foreseeable future somatic cell gene transfer should only be considered for diseases which meet the following criteria; they are caused by a defect in a single gene; they cause a liveborn human being to suffer severe debilitation or early death; they cannot be treated successfully by any other means."

157 "Since there are possible harms to others, it is appropriate to persuade the subject to continue on long term follow-up." *ibid.*, at 26; also see Sub-Committee of the National Council of Bioethics and Human Research, *supra*, note 104 at 33: "After such therapy [Somatic cell gene therapy], follow-up should be made mandatory on a long term basis because withdrawal from such trials is impossible as the therapy cannot be reversed."

to inform fully not only those parents who are eager to use every available technology to help their child, but also those who wish to protect their child from too much technology. It also stated that "[p]rovision should therefore be made in the protocol to ensure the availability of in depth counselling to ensure full understanding by the subject or legal guardian of what is proposed in the protocol".[158] Finally, the report recommended that children participate in the decision-making process to the extent that they are capable. Negative preferences of children should be respected.

Although children should be consulted, they generally do not have the legal capacity to consent and pose particular problems for genetic testing, therapy and research, this notwithstanding the importance our society has placed on individual patient autonomy. The mature minor however, has been accorded greater autonomy in this regard.

(c) ADOLESCENTS

In contrast to this increasingly protective stance towards newborns and hesitancy about including children in genetic therapy and research, the adolescent or mature minor has recently achieved greater autonomy in medical decision-making.[159] Over the last decade, this recognition of the developmental capacity of minors has allowed them to refuse beneficial treatment and to obtain contraception, treatment for sexually transmitted diseases (STDs) and abortion without parental consent. Generally, this autonomy does not extend to non-therapeutic procedures such as sterilization, cosmetic surgery, organ donation, or participation in research. Whether this autonomy goes beyond such ordinary medical treatment and care, to genetic testing, therapy, or even participation in research, is uncertain particularly given factors such as the potential for future stigmatization and the familial nature of genetic information. Testing, however, may well be warranted in the case of familial polyposis coli where removal of the colon in the early teenage years is necessary to prevent cancer.[160] There is no doubt that what has been said about the participation of children and the right to be informed about treatment that is for their benefit or the exclusion from presymptomatic testing where there is no treatment or somatic therapy, applies equally to adolescents.

Adolescents however, may also wish to be informed about genetic status for reproductive purposes (carrier status), or for psychological reasons (for example, where there are affected relatives).[161] Although genetic testing in order to make reproductive decisions,

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158 Medical Research Council of Canada, 1990, *supra*, note 29, at 27.

159 C. Bernard & B.M. Knoppers, *supra,* note 116 at 287; L Glantz, "The Law of Human Experimentation with Children" in M. Grodin & L. Glantz, eds., Children as Research Subjects: Science, Ethics and Law (Oxford University Press,1994). See, also, ASHG-ACMG Report, *supra*, note 129.

160 Wertz et al., *supra*, note 127, at 875.

161 Wertz et. al., *ibid.*; ASHG, *supra,* note 129.

has no health benefits for the minor, it is one of the most common reasons for testing.[162] Authorities note that such testing should be limited to situations in which the potential risk to the minor's offspring is high as is the case with dominant disorders. Accordingly, carrier testing for autosomal recessive disorders is considered unwarranted unless both the minor and the minor's partner have a family history of the disorder.[163]

Carrier testing has been offered to adolescents from ethnic groups identified as being at risk for thalassemia or Tay-Sachs, with no discernible harm. In fact, the minors were able to comprehend the information and found the testing useful.[164] More controversial however, are pilot projects on cystic fibrosis, for example, since the information conveyed is of a probabilistic nature and therefore can only definitively include but not exclude the participant.[165]

Any genetic testing should be preceded by thorough education and counselling about the potential risks of the test, including false positives, false negatives, stigmatization, discrimination, or discovery of misidentified paternity.[166] Finally, it has been suggested that any decisions made by the parent with a physician for a child concerning DNA banking be subject to review and ratification when the child becomes an adolescent (that is, capable).[167] There is no doubt that the physician's primary duty is to the adolescent. Participation in genetic testing and therapy is the personal, autonomous decision of the adolescent. Genetic therapy affecting reproduction (germline therapy) or non-therapeutic genetic research, however, will require additional levels of scrutiny due to the possible irreversible effects and the intra-generational character of such interventions.

(d) Incapable Adults

The final group of possible patients or participants in genetic testing, therapy, or research, are adult patients actually suffering from genetic diseases, such as Huntington

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162 Wertz et. al., *ibid.*, at 879. who point out that the minor should be the primary decisionmaker and should not merely be carrying out parental wishes. Moreover, minors should have a negative right of not knowing at all if they so desire.

163 *Ibid.*

164 S. Zeesman *et al.*, "A Private view of heterozygosity: Eight year follow-up Study on Carriers of the Tay-Sachs Gene Detected by High-School Screening in Montreal" (1984) 18 Am. J. Hum. Genet. 769-778.

165 For an overview of the controversy on carrier screening in high schools see: *Ibid.*; M. DeBraekeleer & M. Melançon, "The Ethics of Cystic Fibrosis Screening: Where do We Stand?" (1990) 47 Am. J. Hum. Genet. 581-582; C. Scriver & T.M. Fujiwara, "Invited Editorial: Cystic Fibrosis Genotypes and Views on Screening are both Heterogeneous and Population Related" (1992) 51 Am. J. Hum. Genet. 943-950; F. Kaplan, C.Clow & C.R. Scriver, "Cystic Fibrosis Carrier Screening by DNA Analysis: A Pilot Study of Attitudes among Participants" (1991) 49 Am. J. Hum. Genet. 240-242; C.L. Clow & C. Scriver, " Knowledge About and Attitudes Toward Genetic Screening Among Highschool Students: The Tay-Sachs Experience" (1977) 59 Pediatrics 86-91.

166 ASHG-ACMG report, *supra*, note 129.

167 Sub-Committee of the National Council of Bioethics and Human Research, *supra*, note 104, at 34.

disease,[168] Alzheimer disease,[169] or Down Syndrome, whose capacity to consent is impaired.[170] Adult patients suffering from various degrees of incapacity have also recently benefited from increased legal protection.[171]

Presymptomatic testing of legally capable adults (who may be rendered incapable subsequently by the late onset of a genetic disease) would fall under the general rules governing the treatment of competent persons. Consent forms for DNA banking or research, however, may have to be of a more anticipatory nature so as to reflect what the individual would or would not authorize in the future when the disease begins to affect mental capabilities. Obtaining consent to confirmatory autopsy following death is particularly important in that it is often the only means of getting a precise diagnosis of the disease. Moreover, initially competent persons may become incompetent during a research protocol. Indeed, it could well be considered the responsibility of the physician to ensure that the at-risk person is aware of choices that will need to be made in the future.[172] For behavioral or mood disorders such as schizophrenia or severe depression, where only the depression is manifest, it is useful to know whether a person is at risk so as to fine-tune medications.[173]

For incapable adults, the general rule is that only therapeutic treatment or research may be performed, though some would argue that minimal or no risk research would also be permissible.[174] Caregivers of incapable adults can act only in the best interests of such adults, and any decision-making authority to provide proxy consent on their behalf, according to some, does not extend to non-therapeutic interventions.[175] Such a position would (as in the case with children) render this population "immune" to any "benefit" from possible research that is related to the particular disease or age group category in the name of protection of that very population. Is diagnostic testing in the absence of treatment, that is, for information alone, a therapeutic service? Where the caregiver is a relative, which is usually the case, is there not a conflict of interest since the genetic information coming from the test will also be

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168 S. Adam & M.R. Hayden, "Prenatal Testing for Huntington Disease: Psychosocial Aspects" in Royal Commission on New Reproductive Technologies, *Technologies of Sex Selection and Prenatal Diagnosis*, Research Studies; no. 4, (Ottawa, Supply & Services Canada, 1993) 21.

169 J. Berg, H. Karlinsky & F. Lowy, eds., *Alzheimer's Disease Research: Ethical and Legal Issues* (Toronto: Thompson Professional Publishing,1992).

170 See *Proceed with Care*, vol. 2, *supra*, note 3, at 853ff.

171 See Civil Code of Quebec, articles 15, 16, 19, 21.

172 B. Godard *et al.*, "Ethical Issues Involved in Establishing a Registry for Familial Alzheimer's Disease" (1994) 8:2 Alzheimer Disease and Associated Disorders 79-93.

173 V. Bulyzhenkov, Y. Christen & L. Prilipko, eds., *Genetic Approaches in the Prevention of Mental Disorders* (Berlin: Springer-Verlag, 1990) at 95.

174 See *Medical Genetics: A Legal Frontier*, *supra*, note 75, at 29.

information relevant to the caregiver?[176] Is consent to DNA banking within the purview of the powers of the caregiver? Likewise, what is the ambit of parental powers and possible liability for "quality of life" decisions with regard to the embryo or the foetus?

4. PARENTAL LIABILITY

Under the traditional common law rules governing negligence, a child is not precluded from suing his parents for prenatal injuries manifest at birth.[177] Indeed, the Ontario *Family Law Act,* specifically provides that "[n]o person is disentitled from bringing an action or other proceeding against another for the reason only that they are parent and child".[178] Logically, parental liability could extend even further back into time to decisions made concerning the testing of the preimplantation embryo, the genetic alteration of the zygote or embryo, and to preconception testing of the future "parents".

(a) PRENATAL INJURY

Given the panoply of genetic testing and information choices available to the foetus, potential liability applies to both physicians and parents. *In utero* genetic therapies, therapeutic research protocols, diagnostic tests (for example, amniocentesis, ultrasound, and chorionic villus biopsy) followed by treatment (or by the avoidance of abortions) as well as surgical interventions on the fetus to correct congenital anomalies before birth can all improve the health of the foetus.[179] So wide is the array of choices when susceptibility testing and testing for late onset disorders (predisposition testing) are added to this list, and so unknown are the consequences for future children, for their families, and for society, that the Canadian Royal Commission recommended that "prenatal diagnosis *not* be offered for genes that increase susceptibility to disease".[180] In contrast, the provision of prenatal diagnosis for presymptomatic testing for late onset *single gene* disorders was not totally ruled out because of the gravity of these disorders, the certainty of their onset, and the general absence of

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175 *Ibid.*; see also the case *E(Mrs.)* v. *Eve*, *supra,* note 112; Medical Research Council, 1987, *supra,* note 29; B. Godard *et al.*, *supra*, note 172

176 See generally, R.J. Sram, "New Ethical Problems Related to Environmental Pollution and Behavioral Changes in Human Population" in Bulyzhenkov, Christen & Prilipko, eds., *Genetic Approaches*, *supra*, note 173, at 94.

177 A. Whitfield, "Common Law Duties to Unborn Children" (1993) 1 Med.Law Rev. 28 .

178 R.S.O. 1990, c. F.3, s. 65.

179 For recent developments of various forms of medical and surgical interventions aimed at correcting problems *in utero* see M.R. Langham & K.M. Reiger, "Advances in Fetal Surgery" (1994) 26 Surgery Annual 193-226.

180 *Proceed with Care*, vol. 2, *supra*, note 3 at 881, rec 259. The issue of susceptibility must be considered within the context of the working definition provided by the Report.

treatment. Testing, however, would be restricted to licensed centres and subject to rigorous and extensive counselling.[181]

Irrespective of the adoption of these recommendations, would the failure to have recourse to these tests, protocols and interventions give rise to civil liability? If available, where the use of these techniques causes injury (without fault on the part of the physician[182]) or reveals an anomaly the parents either refuse to treat *in utero* or to abort, would an actionable harm by the child at birth against the parents exist? Several American authors have argued that prenatal screening be demanded by statute[183] or that knowingly or negligently transmitting a defective gene is a legal harm implying that there is a duty not to bring a "defective" child into the world.[184]

Although there are no data on the impact that the actual or potential legal recognition of a suit by a child against his parents for "faulty" *in utero* genetic choices would have on the marital and familial social fabric, it is not difficult to imagine.[185] Indeed, as early as 1974, a special English Commission recommended that, as a general rule, "legislation should specifically exclude any right of action by a child against his own mother for pre-natal injury".[186] Twenty years later, following extensive consultation and research,[187] the Canadian

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181 *Ibid.* , at 865, rec 256. This position runs *contra* to M. Bloch & M. A. Hayden, *supra,* note 136; See however, S. Adam & M.R. Hayden, *supra,* note 168, at 40: "Despite the complexity of prenatal testing for Huntington disease and the need for in-depth counselling and support, prenatal testing for Huntington disease should still remain a valid option for the small number of individuals who wish to have it." See also M. Cooke, "Ethical Issues of Prenatal Diagnosis for Predictive Testing for Genetic Disorders of Late Onset" in Royal Commission on New Reproductive Technologies, *Technologies of Sex Selection and Prenatal Diagnosis*, Research Studies; no. 4, (Ottawa, Supply & Services Canada, 1993) 1; L. Prior, "Screening for Genetic Susceptibilities to Common Diseases" in Royal Commission on New Reproductive Technologies, *Technologies of Sex Selection and Prenatal Diagnosis*, Research Studies; no. 4, (Ottawa, Supply & Services Canada, 1993) 43.

182 Note that the UK legislation *Congenital Disabilities (Civil Liability) Act, supra* note 12, permits a suit by the child against the physician only if there is fault vis-à-vis the mother. See Law Commission, *supra,* note 12.

183 J.A. Robertson, "Procreative Liberty and the Control of Conception, Pregnancy and Childbirth" (1983) 69 Virginia Law Review 405-64.

184 M. Shaw, "Testing for the Huntington Gene: A Right to Know, a Right Not to Know, or a Duty to Know" (1987) 26 American Journal of Medical Genetics 243, at 245. For a contrary philosophical approach to this issue, see D.W. Brock, "The Non-Identity Problem and Genetic Harms - The Case of Wrongful Handicaps" (1995) 9(3/4) Bioethics 269 who calls the failure of parents to prevent genetic harm when it is possible for them to do so - "wrongful handicaps". He argues that most harms are still compatible with a life worth living and do not necessarily imply that the person with the handicap has been wronged or is a victim with a special moral complaint.

185 For a critique of the notion of genetic rights see Law Reform Commission of Canada, *Human Dignity and Genetic Heritage*, (Protection of Life Series - Study Paper) by B.M. Knoppers (Ottawa: Law Reform Commission,1991) at 29 [hereinafter *Human Dignity and Genetic Heritage*].

186 Law Commission, *supra*, note 12, at 25. Interestingly, the father would not receive any special exemption from liability, the relationship of the mother with the foetus in utero being unique(at.35). In contrast with the position of the Law Reform Commission of Canada, *Crimes Against the Foetus*, (Working Paper 58) (Ottawa: Law Reform Commission of Canada, 1989) where the father has a limited role. See also Law Reform Commission of Canada, *Biomedical Experimentation Involving Human Subjects*, (Working Paper

Royal Commission on New Reproductive Technologies concluded in a similar vein that "civil liability never be imposed upon a woman for harm done to her fetus during pregnancy",[188] "the dangers posed by judicial intervention far outweigh[ing] any benefits that a given individual intervention might yield".[189] Indeed, as rightly noted, "it is ethically (as well as legally) wrong to suggest that pregnant women's rights to make decisions about their medical care and treatment should be changed or lessened because they are pregnant".[190] While this position goes against previous Canadian case law,[191] and most certainly against a growing trend in the United States to prosecute maternal "prenatal abuse",[192] there is a fundamental difference between the possible liability of a physician within a professional relationship for failure to inform about genetic tests or for their negligent performance, and the "genetic" choices that a woman or couple makes during pregnancy.

The emergence of these notions of genetic harms follows upon the advent of insurance and the recognition of family members as persons rather than property (that is, wives and children), the latter trend having eroded the traditional doctrine of marital and parental immunity.[193] Recognizing the dangers to free, personal, reproductive decision making, at least twenty-two American states in the last decade specifically enacted legislation prohibiting wrongful life suits by children against their parents.[194]

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61) (Ottawa: Law Reform Commission of Canada, 1989) [hereinafter Law Reform Commission of Canada, Working Paper 61] at 50 which states that with regard to non-therapeutic biomedical experimentation on embryos "... the consent of both parents should be necessary. It seems important, on the one hand, to underline the fact that a child has two parents and hence to grant the father a right of refusal ..."

187 S. Rodgers, "Juridical Interference with Gestation and Birth" in Research Studies no. 4, *supra*, note 2, 1.

188 *Proceed with Care*, vol. 2, *supra*, note 3, at 964, rec. 273. For a critique on the Royal Commission's position, see S. Martin & M. Coleman, "Judicial Intervention in Pregnancy", (1995) 40 McGill L. J. 947.

189 *Ibid.*, at 962.

190 *Ibid.*, at 957. See, also, S. Bewley, "Legal Frameworks to Prevent Harm in-Utero" (1994) 1 Medical Law International 277-287 who proposes a "hands- off pregnant women" legal framework.

191 For an overview, see J. Olivier, "State Intervention During Pregnancy and Childbirth: The Newest Challenge to Women's Reproductive Freedom" (1993/94) 2:3 Health Law Review 11.

192 Rodgers, *supra*, note 187, at 55ff; See, also, R. Beal, ""Can I Sue Mommy?" An Analysis of a Woman's Tort Liability for Prenatal Injuries to her Child Born Alive" (1984) 21 San Diego Law Review 325; J. Kahn, "Of Woman's First Disobedience: Foresaking A Duty of Care to Her Fetus - Is this a Mother's Crime?" (1987) 53:3 Brooklyn Law Review 807-843; G.M. Bambrick, "Developing Maternal Liability Standards for Prenatal Injury" (1987) 61:4 St. John's Law Review 592-614; N. Hansbrough, "Surrogate Motherhood and Tort Liability: Will the New Reproductive Technologies Give Birth to a New Breed of Prenatal Tort?" (1986) 34 Cleveland State Law Review 311.

193 See Beal, *supra,* note 192; Kahn, *supra,* note 192; Bambrick, *supra,* note 192; Hansbrough, *supra,* note 192; C.A. Simon, "Parental Liability for Prenatal Injury" (1978) 14 Colum. J. L. & Soc. Probs. 60.

194 D.C. Wertz, "Prenatal Diagnosis and Society", in Royal Commission on New Reproductive Technologies, *New Reproductive Technologies: Ethical Aspects*, Research Studies; no. 1 (Ottawa: Supply & Services Canada, 1993), 191, at 285; See also Elias & Annas, *supra,* note 25; also *Medical Genetics: A Legal Frontier*, *supra* , note 75 at 148; *Grodin* v. *Grodin*, 102 Mich. App. 396, 301 N.W.2d 869, (Mich. Ct. App.

The enactment, in 1978, of legislative provisions in the Ontario *Family Law Reform Act*, enabling children to sue after birth for injuries incurred prenatally, codified the case law.[195] That *Act* however, also contains a section stating that "[n]o person shall be disentitled from bringing an action or other proceeding against another for the reason only that they stand in a relationship of parent and child".[196] Furthermore, as recently reiterated , "there was a private law duty of care owed by a parent to her child-in-charge, based on both the foreseeability of risk of harm and the special relationship of proximity between parent and child".[197] The increased availability of information and concomitant genetic choices indicate the potential for parental civil liability and the possible need for a legislative exception to the specific situation of prenatal parental decisions. Such an exception is necessary to avoid abortion pressures, possible eugenic pressures (be they social or economic), and more importantly, to underscore the special fiduciary nature of the parent-child relationship.[198] Genetic choices should not be seen, in retrospect, as "faults". Similar concerns arise in the context of the preimplantation embryo.

(b) PREIMPLANTATION DIAGNOSIS

The pre-embryo can also be the subject of genetic testing. Currently, preimplantation diagnosis is an experimental method of genetic testing involving the removal of cells at the blastocyst stage (before embryonic axe) and thus necessarily involves *in vitro* fertilization.[199] The selection and implantation of embryos free from severe male X-linked disorders or from cystic fibrosis are two known applications of this technique. More recently, such screening is

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1980); *Stallman* v. *Youngquist*, 129 Ill.App.3d 859, 473 N.E.2d 400. See also, *supra*, note 12, for similar U.K. legislation .

195 See *supra*, note 178, s. 66; Rogers, *supra*, note 187. See, also ,"Modern Birth Technology", *supra,* note 46.

196 *Ibid.*, s. 66.

197 *J.(L.A.)* v. *J.(H.)* (1993), 102 D.L.R. (4th) 177 (Ont. Ct.) at181.

198 *Ibid.*, at 182.

199 See *supra,* ch. 2. See, also, F.C. Fraser, "Preimplantation Diagnosis" in Royal Commission on New Reproductive Technologies, *Technologies of Sex Selection and Prenatal Diagnosis*, Research Studies; no. 4, (Ottawa, Supply & Services Canada, 1993) 225 who at 229 notes: "[h]owever, there are problems with this technique. One problem arises because the fertilized egg (with its polar body) results from IVF or is recovered by uterine lavage, which has a limited success rate. In addition, removal of the polar body from the fertilized egg and PCR amplification are not always successful. A second and more fundamental problem is due to a normal genetic phenomenon, crossing over, which is an exchange between homologous chromosomes during meiosis... A third problem is that transferred conceptus may not implant; therefore, this approach has had very limited success." For studies dealing with embryo experimentation generally see: Medical Research Council, 1987, *supra,* note 29 at 32ff.; Law Reform Commission of Canada, Working Paper 61, *supra*, note 185 at 51ff; Ontario Law Reform Commission, Ministry of the Attorney General, *Report on Human Artificial Reproduction and Related Matters* (Ontario: OLRC,1985).

being considered for familial type, late-onset colon cancer.[200] As noted in a 1993 report on genetic testing:[201]

> The appeal of this earliest form of prenatal diagnosis is that it could avoid many of the difficult decisions and potential psychosocial consequences of decisions to selectively terminate a fetus affected with a genetic disorder. Couples at risk of having children affected by diagnosable genetic disorders might be spared repeated decisions in each pregnancy about possible termination of affected fetuses identified at a later stage in fetal development. Very little is known about the technical and biological safety of these techniques.

Indeed, the survival rate is approximately twenty percent compared to ninety-nine percent with prenatal diagnosis. In all likelihood, it is the moral objection to abortion that will attract couples to this technique.[202]

Physicians (and possibly parents, depending on acceptance of intrafamilial genetics suits) could be liable for wrongful life if "negligent preimplantation diagnosis resulted in implantation of an affected pre-embryo".[203] Furthermore, in contrast to prenatal diagnosis where respect for the autonomy of the woman is both a legal and ethical norm, one author has noted that "in the absence of clear law on the status of a pre-embryo *in vitro*, property law principles may be applicable.... [Moreover] laws equating the pre-embryo with a born child and invoking for instance, 'best interests' concepts regarding custody and protection against child abuse quickly lead to absurdity, as U.S. legislative and case-law experience has shown. Contractual arrangements between physicians and gamete sources should be required or encouraged, and in principle their terms should prevail."[204]

Two issues are raised by such a contractual approach. Firstly, one would assume that the "parents" of the pre-embryo must both consent and secondly, in the absence of any legislative framework, would be free to make any arrangements that did not run afoul of

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200 Although preimplantation testing has generally focused on gene mutations that cause severe disease in childhood or early adulthood, it may potentially be used to screen for genes that increase the risk of developing cancer later in life. Embryos, conceived through in vitro fertilization, may be tested for example, for an inherited form of bowel cancer called familial adenomatous polyposis (FAP), also known as adenomatous polyposis coli. People inheriting a single copy of the gene responsible have an 80 to 90 per cent chance of developing the disease by the time they are in their forties. FAP can be treated by removing the lower bowel but tumours often subsequently occur in other parts of the body, where they are usually lethal. See G. Vines, "Every Child a Perfect Child?", (Oct. 1995) New Scientist 14-15; R. Highfield, "Test-Tube Embryos to be Screened for Cancer", (3 October, 1995) The Daily Telegraph.

201 Committee on Assessing Genetic Risks, *supra*, note 13, at 82.

202 Fraser, *supra*, note 199, at 230. Also, it is interesting to note that while many couples may reject abortion on moral or religious grounds, they can accept the manipulation, selection and risks involved with preimplantation diagnosis.

203 B.M. Dickens, "Legal Issues in Embryo and Fetal Tissue Research and Therapy" in Royal Commission on New Reproductive Technologies, *Background and Current Practice of Fetal Tissue and Embryo Research in Canada*, Research Studies; no. 15, (Ottawa, Supply & Services Canada, 1993) 43, at 46.

204 *Ibid.*, at 47.

public policy. Whereas decisions whether or not to implant or to test should remain those of the couple, the framework for such testing, and the types of conditions tested for, need more than just medical or ethical oversight in order to avoid abuse. Indeed, the possibility of using preimplantation diagnosis for non-medical purposes such as determination of sex is but one example. The Canadian Royal Commission recommended that "[t]he National Reproductive Technologies Commission guidelines for licensed *in vitro* fertilization clinics prohibit the use of preimplantation diagnosis to determine fetal sex for non-medical reasons. [Furthermore], [a]dherence to these guidelines should be a condition of licensing by the (proposed) National Reproductive Technologies Commission".[205] In the absence of a prohibition of wrongful life suits against parents for genetic choices, parental autonomy, responsibility and possible liability remain important issues. Preimplantation testing then is an area where parental reproductive decision-making may well need to be circumscribed.

(c) GENETIC ALTERATION

The issue of "parental" autonomy is also important in the decisions surrounding the genetic alteration of a zygote or embryo prior to implantation. As discussed,[206] alteration involves the introduction of genetic material with the hopes of correcting a genetic disorder. The most common type of alteration is somatic cell gene therapy, which is considered to be like any other "therapeutic" intervention since it treats the genetic condition in that individual and does not affect the germ line cells. Somatic therapy does not raise novel legal issues beyond those generally associated with other types of biomedical experimentation.[207] As discussed earlier, current trials are centered on children.[208] The indicators for either fetal or embryonic somatic treatment are rare and, in the latter case, the choice may well be not to implant the embryo. Fetal somatic therapy however, raises concerns since again there may be pressures on the woman to ensure the genetic "health" of the fetus. Any Canadian trials should require more than just local or provincial approval.[209]

In contrast, genetic alteration involving the germ cells of an *in vitro* embryo thereby eliminating the "defect" forever, remains highly controversial and almost universally condemned.[210] Moreover, it is questionable whether such "therapy" is really necessary

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205 *Proceed with Care*, vol. 2, *supra*, note 3, at 907, rec. 265.

206 See *supra*, ch. 2.

207 Prior, *supra*, note 181, at 250. See, also, Ontario Law Reform Commission, *supra*, note 199; Medical Research Council, 1990, *supra* , note 29. See, also, discussion in *Proceed with Care*, vol. 2, *supra* , note 3, at 931-936; also, C. Coutelle, et. al., "The Challenge of Fetal Gene Therapy", (1995) 1(9) Nature Medicine 864.

208 See text accompanying note 158ff.

209 This is the position of Medical Research Council, 1990, *supra*, note 29, and in *Proceed with Care*, vol. 2, *supra*, note 3 at 936, rec. 267 and 268.

210 Note change however in position from outright prohibition to more recent permissive attitude. R. Munson & L.H. Davies, "Germ-line Gene Therapy and the Medical Imperative" (1992) 2:2 Kennedy Institute of Ethics Journal 137-158.

considering the fact that the simplest choice may well be not to implant the embryo at all. Testing on the oocytes or sperm may also be a possibility and raise fewer ethical concerns.[211] These futuristic options may not be in accord with personal values or respect for human life, and the "risks and potential harms" of intentional interference in human evolution are so great that the Royal Commission recommended prohibiting both research and any possible applications of germline genetic alteration in Canada.[212]

(d) Preconception Testing

At first glance, there is a greater degree of autonomy, privacy and freedom of reproductive decision-making in genetic testing when performed at the request of individuals for personal, medical information. This ambit may be considerably lessened however, when the reason for testing is personal knowledge of genetic conditions in the family or, of those conditions associated with a particular race, ethnic group or even specific populations.[213] Such individuals (alone or with their partners) will come to be tested for carrier status or to see if they themselves are or will be affected. Similarly, couples having a previous child with a disorder, or coming from families at risk may also seek preconception testing. Knowledge of the genetic condition in question makes these individuals, couples or communities particularly sensitive to the "handicapping" socio-economic environment of genetic conditions. When organized by the communities themselves, screening programs specific to the condition have been successful.[214] We have seen that where physicians know or should know of particular indicators for genetic conditions, there may be a duty to advise of the existence of preconception tests, but is there a duty to be tested on the part of future spouses, or indeed, on anyone choosing to have a child?

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211 Cooper & Schmidtke, *supra*, note 62, at 40-41.

212 *Proceed with Care*, vol. 2, *supra,* note 3, at 835, rec. 241, at 942 rec. 260 and 270. The Royal Commission on New Reproductive Technologies also criticizes the misunderstandings of the science itself. See at 940: "The idea of eliminating the risk of transmitting the genetic disease may sound attractive, but it is in fact based on misunderstandings of human genetics. All of us are carriers of various recessive genetic disorders - that is we all carry genetic mutations that, if found in double dose, could be deleterious, even fatal. To set as our aim the elimination of all risks of passing on genetic disease would involve genetic alteration of the gametes or gonads of all adults."

213 See *supra,* ch. 2. With respect to personal knowledge of genetic conditions within a family, predictive testing, for example, can be done for someone thought to be at risk for HD. However, it is relevant for that person to know whether their affected parent or other family member really has HD (with an 'expanded' gene). Otherwise, a negative test result may actually be uninformative with respect to the true cause of symptoms. Do they therefore have the right to such information about their (possibly incompetent) relative?

214 For example, in the early stages of screening programs for Tay-Sachs disease, testing was concentrated through large community clinics often organized by Jewish community organizations. These were highly successful and large numbers of high risk persons and at risk couples were tested. When attendance began to fall, by the mid 1970s two alternative approaches were adopted. In Toronto, a case-finding approach was developed. It relied upon the referral of persons at-risk by their family physician, obstetrician, rabbi etc. J.T.R. Clarke, R.A. Gravel & D.J. Mahuran, "Carrier Screening for Tay-Sachs Disease: Prospects for Direct Mutation Analysis" in *Genetic Screening*, *supra,* note 98, 179-196, at 180. The second approach, developed in Montreal, was the mass screening of teenagers in high-school testing programs. See Clow & Scriver, *supra*, note 165.

Reproductive "genetic roulette" will always continue, genetic disorders being normal to the human condition. If, however, personal, familial or community experience makes for awareness of potential risk, is there any duty to act? If so, is it to act in an "informed" way by not reproducing, seeking donor gametes, adopting, or, if available, by going for preimplantation testing, that is, avoiding transmission of the condition? If testing for a heritable condition in an adult is positive, is the deliberate conception of a child (where there is a fifty percent chance that a disorder will be present at birth), a negligent act? What if it is a late onset condition, a heightened susceptibility or, only a "minor" disorder? Because these decisions are made prior to reproduction, is there greater parental responsibility and thus possible liability?

The availability of testing is not synonymous with a duty to be tested or even to act on the results. Although there are no reported cases of preconception parental negligence suits, the same policy concerns that surround prenatal testing, preimplantation testing and gene alteration arise.[215] The freedom underlying deliberate conception that may result in an affected child may well be the ultimate bulwark against incremental eugenics through policies or laws limiting such fundamental choice.[216] Again, that choice may have to be protected by shielding parents from possible future legal incriminations by the child as to the quality of life choices made before his or her conception.

5. CONCLUSION AND RECOMMENDATIONS FOR REFORM

There is no doubt that both the familial nature and the larger social issues surrounding genetic testing place new duties on physicians and parents, while expanding traditional ones. Does the physician now have the whole "genetic family" as a "patient"? If providing information becomes the treatment, to whom is the duty to inform owed? If DNA banking is considered part of the treatment, the same question arises. There are no clear guidelines with respect to possible liability for genetic testing (or not) with vulnerable populations. Parents and "potential" parents may not be immune from suits for "genetic faults" and for not having acted in the best interests of their children. Finally, no provincial or federal government has adopted the Royal Commission recommendations concerning the oversight of laboratories and testing, of restriction or prohibition with regard to certain tests such as sex-selection, or of certain activities such as germ cell line alteration.

Other unanswered questions remain: should the uncharted recourse of genetic duties and genetic liability be defined by plaintiffs and the courts within ordinary negligence actions? Should the larger social issues and the delicate fabric of familial relations be considered? Or should the parameters of genetic responsibility and genetic liability be defined more explicitly by legislative and professional bodies? Certainly, as far as reproductive freedoms are concerned, there is an evident need for statutory protection to ensure free choice.

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215 See the discussion *supra*, this ch., sec. 4. See, also, Robertson, *supra*, note 183; Shaw, *supra*, note 184.

216 See *supra*, ch. 3.

In genetic testing, respect for free and informed procreative decision-making, for vulnerable populations, for the freedom and responsibility inherent in "professionalism", and for the basic values of a given society also form the background against which the extent of potential physician or institutional liability for genetic malpractice must be situated and measured. Neither the courts, the physician, nor the patient, can be the sole arbiters of genetic malpractice. Genetic malpractice is not a simple extension of general malpractice rules. The *ex post facto* imposition of genetic duties and the spontaneous creation of "genetics rights" are too onerous in their social consequences to be left to individual cases making their way through the courts. Accordingly, the Commission recommends that the Ministry of Health should establish regulations that prescribe minimum or appropriate standards for genetic testing, personnel training and education in the area of medical genetics, and the accreditation of genetic laboratories. Quality assurance, which provides an independent audit of a laboratory's testing results by an outside independent expert laboratory, is particularly important, not only with respect to the issue of human rights, but also given the ethical, social and financial consequences of genetics testing.

The Commission further recommends that physician and institutional liability to parents and children in the area of genetic testing should be left to general malpractice rules, and that professional associations should study the ambit of a possible duty to recall or to "look-back".

The Commission has concluded, and therefore recommends, that explicit parental consent should not be required for newborn screening for diseases that are immediately treatable but irreversible if left to be discovered clinically. However, the Commission also recommends that the banking of newborn screening data and samples should be subject to parental consent, and to quality assurance and oversight specifically given the need to ensure storage for legitimate research purposes. Professionals should again consider a possible duty to recall. Where there are no timely medical or psychosocial benefits, or where these benefits will not accrue until adulthood (as in the case of carrier status or adult-onset diseases), the Commission recommends that children should not be tested for genetic conditions. Where the balance of benefits and harms is uncertain, and the family requests testing, such requests should be presented to an ethics committee (possibly the hospital's own committee, where available) for determination.

Mature minors, in the Commission's view, should be able to make their own decisions with regard to genetic testing, following the provision of all appropriate information, including genetic counselling, and the Commission so recommends. Finally, the Commission recommends that wrongful life suits by children against their parents should be prohibited by legislation. Although a child has the ability to sue a parent under the *Family Law Act* generally, a suit for wrongful life against a parent would infringe upon the parents' constitutionally protected right to conceive and give birth as well as the inherent dignity and worth accorded all human beings. Therefore, there should be statutory immunity from liability for any "genetic" choices made.

CHAPTER 9

PRIVACY AND CONFIDENTIALITY

1. INTRODUCTION

The recent scientific rush to map the human genome, which has produced major scientific advances in diagnostic testing for genetic disease, may soon lead to a whole new category of sensitive information being included routinely in a patient's medical dossier. Whereas health care providers once recorded data about a patient's medical past and present in order to treat a current condition, genetic information, due to its probabilistic and relative predictive nature, can be used as a blueprint for the patient's health management or reproductive options in the future. Similarly, whereas physicians once broadly questioned a patient about familial medical history but concentrated mostly on the individual's condition, genetic test results, in so far as they may be conclusive, may bring the health status of a group of biological relatives into sharp focus.

Institutions and health care providers dealing with genetic information must therefore adapt to the reality that such data differs from that contained in other types of medical records. Among the major differences between the two types, are the following: (1) genetic testing can reveal much more personal information than other types of medical testing and evaluation methods; (2) genetic testing can reveal to individuals "futuristic" medical predictions; (3) genetic disorders generally affect people throughout their lives and thus, knowledge of genetic information can have a dramatic impact on individuals; (4) the development and availability of genetic information could have potentially serious adverse financial, emotional, and social consequences; (5) genetic testing may reveal information about other family members as well as information about the individual tested;[1] and (6) genetic information is itself unique from other types of medical information in that it has its own social, historical, and political perspectives.

As researchers develop diagnostic tools for a myriad of diseases with genetic components, and as such tests eventually become accepted medical practice, the need to examine genetic privacy and confidentiality, in particular the protection of sensitive genetic

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1 M. Powers, "Privacy and Control of Genetic Information" in (M.S. Frankel and A.H. Teich , eds.), *The Genetic Frontier: Ethics Law and Policy* (Washington, DC: American Association for the Advancement of Science, 1994) at 80. See also Alexander Capron, "Unsplicing the Gordian Knot: Legal and Ethical Issues in the "New Genetics" in (A. Milunsky and G.J. Annas, eds.) Genetics and the Law III (New York: Plenum Press, 1985) 23 who points out " a technology that might peer into our genes and even transform them cuts to a deeper level of psychological significance than do others in biomedicine, however technically spectacular they may be".

information contained in health records from third parties, is very real. It has been written that "genetic knowledge of an individual is, in one important sense, as deep as one can go in the discovery of that individual".[2] It is thus clear that such information merits special protection and safeguards from unauthorized disclosure perhaps even above and beyond the confidentiality framework that has evolved to protect other types of medical information.

There may be cases, however, in which third parties have legitimate claims to disclosure. For instance, in the context of familial relationships, where genetic traits and conditions are hereditary and therefore shared, new strains may be placed upon caregivers and keepers of medical records, whose legal and ethical duties of confidentiality have traditionally been constructed upon individualistic notions of personal privacy. Although the information may have been obtained through one person's initiative to be tested, results may concern several individuals and can be the key to their present and future health care. Physicians and other health care providers confronted with an individual who refuses to share such crucial health information with blood relatives who may or may not be affected by a genetic disorder, face a disturbing moral and ethical choice: that of respecting their patient's privacy and confidentiality or that of making a unauthorized disclosure to family members in order to avoid any harm from coming to them.

Employers and insurers may have less of a compelling moral claim on genetic information, but may claim interests in workplace safety and occupational hazards, as well as in fair underwriting practices, respectively. They may obtain genetic test results from other sources or may themselves proceed with testing, particularly as the technology evolves and becomes more cost-efficient to obtain required information. For instance, employers, in the course of an occupational health and safety program, may be obliged to collect genetic data about workers and the confidentiality of such information within the workplace may well be cause for concern.[3] For their part, since insurers require full disclosure in order to assess risk, confidentiality issues may again arise if applicants are requested either to disclose prior genetic test results or undergo specific testing before a risk will be accepted.[4] The enactment of general legislation protecting privacy and access to health care information as well as providing uniform testing policies will go a long way in preventing any breaches of confidentiality or privacy with regard to general medical and genetic data in either of these contexts.

Many foreign jurisdictions and international organizations have examined questions related to genetic privacy and confidentiality and have formulated recommendations that attempt to balance patients' expectations of privacy with other parties' claims to sensitive genetic information. Views are divided between those jurisdictions that make limited allowances for disclosure of genetic test results without the consent of the patient, in cases

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2 P. Boddington, "Confidentiality in Genetic Counselling" in (A. Clarke, ed.) *Genetic Counselling: Practices and Principles* (London: Routledge, 1994) 223 at 229.

3 See *supra*, ch. 7.

4 See *supra*, ch. 6.

where the risk to relatives is grave and imminent ,and those that maintain that confidentiality and the necessity of trust in the doctor-patient relationship require that the tested individual's wishes as to non-disclosure be respected at all times.

The World Medical Assembly, in its Declaration on the Human Genome Project, allows only relevant information to be disclosed[5] when attempts to obtain consent have failed and there is a risk of serious harm that is otherwise avoidable. Similarly, the World Health Organization, in its recent guidelines on medical genetics and genetic services, recommends that confidentiality of genetic information be maintained except where there is a high risk of serious harm to family members at genetic risk and the information could be used to avert this harm.[6]

At the regional level, the European Parliament resolved in 1990 that no doctor shall have the right to inform family members without the consent of the individual tested.[7] Similarly, the Council of Europe stated in 1990 that confidentiality must be ensured at all times and that consent was required to communicate genetic information to the other member of a couple. Nevertheless, in 1992, it did make allowances for disclosure in cases of severe genetic risks affecting family members.[8]

Within Great Britain, opinions concerning the confidentiality of genetic screening results diverge. The Nuffield Council on Bioethics recommends that accepted standards of the confidentiality of medical information be followed as much as possible; that should a patient refuse to disclose test results to family members, the physician should stress the importance of sharing such information and attempt to persuade the individual to allow disclosure; and finally, that only in exceptional circumstances may an individual's desire for confidentiality be overridden, but such a decision can be made only on a case by case basis.[9] The members of the Science and Technology Committee, however, disagree with the suggestion that confidentiality should be less than absolute. The Committee is of the opinion

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5 44th World Medical Assembly, Declaration on the Human Genome Project, Marbella Spain, September 1992, (1992) 44 (2) *Int. Digest Health Legis.* 150.

6 D.C. Wertz et al., *Guidelines on Ethical Issues in Medical Genetics and the Provision of Genetic Services,* (Geneva: World Health Organization, 1995) (Forthcoming).

7 European Parliament, "Resolution on the Ethical and Legal Problems Of Genetic Engineering" (1990) *Bull. Med. Ethics* at 8.

8 Council of Europe, "Recommendation No. R. (90) 13 of the Committee of Ministers to Member States on Prenatal Genetic Screening, Prenatal Genetic Diagnosis and Associated Genetic Counselling", (1990) *Int. Digest Health Legis.* 41(4), 615; "Recommendation No. R(92)3 of the Committee of Ministers to Member States on Genetic Testing and Screening for Health Care Purposes", (1992) *Int. Digest Health Legis.* 43(2) 284.

9 Nuffield Council on Bioethics, *Genetic Screening: Ethical Issues*, (London: N.C.B, 1993) at 89-90.

that if counselling cannot persuade someone to consent to sharing information with their relatives, the individual's decision to withhold information should be paramount.[10]

The Health Council of the Netherlands is of the view that unauthorized disclosure may be permissible under limited circumstances when serious harm can be avoided, and adds that the relatives' right to privacy should be a consideration when deciding whether or not a disclosure should be made.[11]

Other jurisdictions make no allowances for unauthorized disclosure. Norway, for instance, has taken a firm and clear stand on protecting personal privacy with no exceptions being made for disclosure, even under extreme circumstances.[12] In order to avoid any possible breaches of confidentiality, the Ministry of Health and Social Affairs determined "that information on the genes of people regarded as healthy must remain strictly confidential. Such information must not be stored, not even by health institutions in patient records."[13] The Swiss Academy of Medical Sciences and France's Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé have established guidelines that do not permit disclosure without the patient's consent.[14] The French law of July, 1994 provides that even where genetic testing for medical purposes is exceptionally undertaken without the person's consent, for example, in epidemiological studies, confidentiality will be maintained.[15]

In the United States, attempts at the federal level in 1990 to enact a bill entitled the *Human Genome Privacy Act*[16] were unsuccessful. The bill, which would have provided specific protection of genetic data held by government agencies, was eventually replaced by the much broader *Fair Health Information Practices Act,*[17] which protects all health

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10 Science and Technology Committee, *Human Genetics: The Science and its Consequences*, (House of Commons, 6th July 1995) at para. 227-228.

11 Committee of the Health Council of the Netherlands, *Heredity: Science and Society*, (The Hague: HCN, 1989).

12 Norway: Ministry of Health and Social Affairs, *Biotechnology Related to Human Beings* (1993), at 64. Norway: The Act Relating to the Application of Biotechnology in Medicine, 1994, in Bull. Med. Eth. 8-11 (June July 1994) art. 6.7.

13 *Ibid.*

14 Swiss Academy of Medical Sciences, "Medical-Ethical Guidelines for Genetic Investigations in Humans" (1993) *Bull. Med. Suisses* 74 (No. 38) 1454, Guideline 3.7; Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé, *Avis sur l'application des tests génétiques aux études individuelles, études familiales et études de population (Problèmes des "banques de l'ADN, des "banques" de cellules et de l'informatisation des données)*, 24 juin 1991.

15 Law No. 94-654 of 29 July 1994 on the donation and use of elements and products of the human body, medically assisted procreation and prenatal diagnosis, (1994) 45:4 *Int. Digest Health Legis.* 473, Title VI, A.L. 145-15.

16 H.R. 5612, 101st Congress, 2d session.

17 H.R. 4077, March 17 1994.

information held by such agencies. In 1995, a model act, The Genetic Privacy Act, was drafted as another attempt to propose genetic specific privacy legislation. It recommends that disclosure of private genetic information be prohibited without written authorization and that such authorization apply to persons who create, maintain or furnish private genetic information as part of their ordinary business or professional activities.[18]

We will examine the current legal framework in Ontario relative to privacy and confidentiality, in particular, its application to the security of medical records as well as to the duties of physicians and other health care providers. We will then explore the possible application of a duty to warn family members at risk of genetic test results, should a patient refuse to consent to such disclosure. Finally, we will propose recommendations that ultimately go beyond the specific confines of reform in the area of genetic information and extend to medical information generally.

2. PRIVACY RIGHTS AND THE CONFIDENTIALITY OF MEDICAL INFORMATION IN CANADA

The legal framework that protects personal, medical, or genetic information is complex and stems from a number of sources. Privacy, being a broad notion, which has thus far defied clear definition, is only one theoretical component in a web of measures designed to protect, albeit sometimes inadequately, information from those who are not entitled in law to be privy to it. The law of confidentiality, which sets out a more specific system for protecting personal data in the medical context, may work well in theory but in the context of genetic medicine raises some delicate dilemmas, which will be discussed below.

(a) THE RIGHT TO PRIVACY

In Canada, the right to privacy is an ambiguous concept, which may exist in a number of situations. Some of the theoretical challenges surrounding this legal protection include difficulties in defining the right, confusion between concepts of privacy and confidentiality, which are often used interchangeably, as well as the multiplicity of legal sources from which such a right could stem, particularly in a federal system such as our own.

A number of attempts to provide a general definition for the right to privacy and its scope have been made over time. Much of the difficulty in defining such a right stems from the multifaceted aspects and applications of such a right. Two commonly recognized dimensions of the right to privacy are particularly relevant to the context of genetic testing: first, protection against physical intrusions against the person, and second, and more importantly, the right to control information about oneself.[19] The right to physical or bodily

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18 G.J. Annas, L.H. Glantz & P.A. Roche, Proposal: *The Genetic Privacy Act and Commentary* (Boston: Boston University School of Public Health, 28 February 1995) secs. 111(a), 112 & 132 (a).

19 E.L. Oscapella, "Overview of Canadian Laws Relating to Privacy and Confidentiality in the Medical Context" in *Overview of Legal Issues in New Reproductive Technologies* (Research Studies of the Royal Commission on New Reproductive Technologies, vol. 3) (Ottawa: Minister of Supply and Services Canada, 1993) 172 at 172-173. See also Karen Lebacqz, "Genetic Privacy: No Deal for the Poor" (1994) 33(1)

privacy could protect an individual from physically invasive procedures (in genetic medicine, usually blood sampling) to obtain genetic data, whereas the informational aspect of privacy could protect the data or test results themselves from use by third parties through various mechanisms of control. Informational privacy has thus been defined in Canada as "the claim of individuals, groups or institutions to determine for themselves when, how and to what extent information about them is communicated to others".[20]

Prohibitions or restrictions on the collection of data, restrictions on the use made of data, and the imposition of obligations of confidentiality to prevent unwarranted disclosure of the information collected are the three main ways that informational privacy can be protected.[21] In view of the complexity of the legal framework surrounding informational privacy, as well as the different ways it can be protected, a number of legal sources must be examined.

First and foremost, it is important to note that there is no *a priori* constitutionally sanctioned right to privacy in Canada. However, sections 7 and 8 of the *Canadian Charter of Rights and Freedoms,*[22] have been cited as creating limited and implicit rights to privacy. Section 7 protects individuals' "life, liberty and security of the person" whereas section 8 provides protection from unreasonable search and seizure and ensures a reasonable expectation of privacy as was outlined in *Hunter* v. *Southam.*[23] The section 8 guarantee has been found to protect three zones of privacy: (1) territorial or spatial (property); (2) privacy of the person (from physical search and indignity); and (3) informational privacy, the assumption being that all information about a person is in a fundamental sense his own, for him to choose whether to share or to keep for himself.[24] Both rights are necessarily subject to the reasonable limits test of section 1. In a medical context, the Supreme Court of Canada found, in the *Dyment*[25]case, that the seizure of a criminal suspect's blood, which contained

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Dialog 39 at 40 who notes that genetic privacy encompasses three notions: a right not to know one's genetic status if one so chooses, a right not to tell others or to have others know, and a right to use genetic information to make decisions within the framework of one's own values. She further points out that all three of these notions get challenged by the social, cultural and practical realities in which we live.

20 Ontario, Commission of Inquiry into the Confidentiality of Health Information (Hon. Mr. Justice Krever, Commissioner) *Report of the Commission of Inquiry Into the Confidentiality of Health Information* , vol. 1 (Toronto: Queen's Printer, 1980) at 6 (Hereinafter *Krever Commission Report*).

21 Oscapella, *supra*, note 19, at 173-174. See also D.M. Robinson, "Health Information Privacy: Without Confidentiality", (1994) 35 (Suppl.1) International Journal of Bio-Medical Computing 97-104 at 100 who argues that privacy could be significantly improved if a policy of absolute confidentiality of all health information was replaced with a policy of anonymity of patient specific information. He also points to the Canadian National Institute for Health Information as an example of the trend for administering health information networks in which protection of privacy is needed for its efficacy.

22 Part 1 of the *Constitution Act*, 1982 being Schedule B of the *Canada Act,* 1982 (U.K). c. 11. (Hereinafter the *Charter*).

23 [1984] 2 S.C.R. 145.

24 *R.* v. *Dyment*, [1988] 2 S.C.R. 417.

25 *Ibid.*

information pertaining to his blood alcohol level, was illicit. While there may have been some judicial findings of implicit privacy rights under the *Charter*, it is important to note that they have occurred in the criminal law context of impaired driving offences and that the reach of these sections into non-criminal matters remains to be determined.[26] Furthermore, the *Charter* provides protection only from government acts or legislation and does not reach to private sector physician-patient relationships.[27]

At the federal level, a data protection statute regulating the collection, use, disclosure, and access to personal information held in government records came into force in 1983.[28] The *Privacy Act* sets out specific protections for personal information, which may include health information about an identifiable individual.[29] The main criterion for permitting the collection of data is relevance to an operating government program or activity and normally information must be collected directly from the person to whom it relates.[30] Disclosure of personal information is regulated by section 8(1), which sets out a general rule of consent by the individual whom the information concerns. Section 8(2), however, enumerates a number of exceptions to the rule of confidentiality, among them the following: disclosure for the purpose for which the information was obtained or compiled; where a federal law or regulation permits it; to comply with a warrant, court order or subpoena; to an investigative body; to foreign states of organizations of states under an agreement; if such disclosure is deemed to be in the public interest or for research purposes.

Ontario's data protection statute, the *Freedom of Information and Protection of Privacy Act*[31] regulates the collection, use, and disclosure of personal information by provincial institutions such as government ministries, agencies, boards, commissions, corporations and other bodies designated as institutions under the regulations.[32] Similar provisions have been extended to the municipal sector through the *Municipal Freedom of Information and Protection of Privacy Act,*[33] which applies to locally operated public health boards and school

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26 Oscapella, *supra,* note 19, at 181. The uncertainty of the extent to which a privacy right might apply to non-criminal matters is evidenced in the recent case of *Canadian AIDS Society* v. *Ontario* (1995) O.J. No. 2361 (Ont. Gen. Div.) (not yet reported) where the Court held that while there is a constitutional right to privacy in the civil law context found in ss. 7 and 8 of the *Charter* which the mandatory HIV reporting requirements of the *Ontario Health Protection and Promotion Act* ostensibly violated, these requirement were (a) consistent with the principles of natural justice, and therefore did not violate s. 7 of the Charter, and (b) reasonable, and therefore did not violate the "unreasonable search and seizure" provisions of s. 8.

27 *Supra*, note 19, s. 32 and *Retail, Wholesale & Department Store Union, Local 580, et. al.* v. *Dolphin Delivery Ltd.*, [1986] 2 S.C.R. 573.

28 *Privacy Act*, R.S.C. 1985, c. P-21.

29 *Ibid.*, s. 3.

30 *Ibid.*, ss. 4-5.

31 R.S.O 1990, c. F.31

32 Agencies covered by the act are listed at R.R.O 1990, Reg. 460 and include the Advisory Committee on Genetic Services operated by the Ministry of Health.

33 R.S.O 1990, c. M.56.

boards, which often keep records containing sensitive health information. These provisions do not extend to bodies without some governmental component or to doctors in private practice, private clinics, university research labs, the vast majority of hospitals and genetic centers, private labs or data banks.[34]

Such laws attempt to strike a balance between the public's right of access to information under the control of governmental institutions and individuals' right to privacy when personal information is held in state records. Their objective is to regulate the flow of information within and being released by the government sphere. The provincial act grants a right of access to two types of government-held information: government records; and personal information, which is defined as recorded information about an identifiable individual. This second category is relevant to health records and genetic information since the law provides for protection of information pertaining to the medical history of an individual or his or her fingerprints or blood type, which could perhaps eventually be interpreted to mean a DNA Profile.[35]

Generally, personal information must not be disclosed to any individual other than to whom that information relates. Such a refusal is justified on the basis of that person's right to privacy, however section 21(1) of the *Freedom of Information and Protection of Privacy Act* does enumerate circumstances in which disclosure can be made:

> 21.—(1) A head shall refuse to disclose personal information to any person other than the individual to whom the information relates except,
>
> (a) upon the prior written request or consent of the individual, if the record is one to which the individual is entitled to have access;
>
> (b) in compelling circumstances affecting the health or safety of an individual, if upon disclosure notification thereof is mailed to the last known address of the individual to whom the information relates;
>
> (c) personal information collected and maintained specifically for the purpose of creating a record available to the general public;
>
> (d) under an Act of Ontario or Canada that expressly authorizes disclosure;
>
> (e) for a research purpose if,
>
> (i) he disclosure is consistent with the conditions or reasonable expectations of disclosure under which the personal information has been provided, collected or obtained,
>
> (ii) the research purpose for which the disclosure is to be made cannot be reasonably accomplished unless the information is provided in individually identifiable form,

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34 *Supra*, note 31, s. 2(1).

35 *Ibid.*, s. 2(1).

(iii) the person who is to receive the record has agreed to comply with the conditions relating to security and confidentiality prescribed by the regulations; or

(f) if the disclosure does not constitute an unjustified invasion of personal privacy.

Section 21(2) of the Act sets out a number of criteria to determine whether disclosure of personal information constitutes an unjustified invasion of personal privacy. Specifically relevant to genetic data are the following:

21.—(2) A head, in determining whether a disclosure of personal information constitutes an unjustified invasion of personal privacy, shall consider all the relevant circumstances, including whether,

....

(b) access to the personal information may promote public health and safety;

....

(e) the individual to whom the information relates will be exposed unfairly to pecuniary or other harm;

(f) the personal information is highly sensitive;

These and the other factors enumerated in the section are guidelines to be considered by the person making the discretionary decision to release personal information and allow the official to make a purely subjective analysis of how each factor should be weighed against each other. The law, however, does provide an additional safeguard to protect medical information, in that section 21(3)(a) establishes a presumption that the disclosure of data pertaining to "medical, psychiatric or psychological history, diagnosis, condition, treatment or evaluation" constitutes an unjustified invasion of privacy, unless there are overriding public policy concerns.

As we have noted, data protection legislation, at either the federal or provincial level, is quite narrow in scope, as it protects and circumscribes access only to health information, medical, genetic or otherwise, contained in public records. For the protection of privately held records, which undoubtedly constitutes the bulk of health information in Ontario, we must turn to the legal and professional duties of confidentiality of physicians, as well as to a limited number of statutory provisions that regulate standards of record-keeping in certain health care institutions and facilities.

(b) Medical Confidentiality

Confidentiality is "a tool for protecting the privacy of information"[36] and has been defined as "an obligation owed by one person not to disclose information given by or about

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36 Oscapella, *supra,* note 19, at 174.

another, or to disclose it only in limited circumstances".[37] There are a number of justifications for health professionals' duty of confidentiality. The first identifies personal privacy as an important societal value, which the practice of maintaining confidentiality can promote or protect. The second is the commonly held view that, without an expectation of confidentiality, patients will be less forthcoming than otherwise in disclosing sensitive personal information that might be key to making diagnoses or providing necessary treatment. Thus, there is an expectation that the information revealed will be used for one purpose, that of ensuring the health and well-being of the patient. In essence, the duty of confidentiality contributes to building a necessary bond of trust between a doctor and a patient.[38]

In Canada, the confidentiality of medical information communicated to a doctor or held in medical records is governed by ethical guidelines and legislation. We will therefore examine the legal framework that creates a duty of confidentiality on the part of the physician and protects such health information from third parties, legal exceptions to the rules of confidentiality, as well as existing legal remedies should confidentiality be breached outside of the current framework of accepted exceptions.

In the case of *McInerney* v. *MacDonald*,[39] the Supreme Court of Canada recently examined Canadian medical practices with regard to record keeping and patient access to information. It ruled that, while the physical records belong to the physician or to the health care institution, the patient has a legitimate claim to the data contained in his or her file. In examining the sensitivity of health care information, La Forest, J. wrote:[40]

> [M]edical records contain information about the patient revealed by the patient, and information that is acquired and recorded on behalf of the patient. Of primary significance is the fact that records consist of information that is highly private and personal to the individual. It is information that goes to the personal integrity and autonomy of the patient.

In this light, the judgment also explored the nature of the physician-patient relationship, which was qualified as fiduciary in nature: [41]

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37 *Ibid.*

38 R. Macklin, "Privacy Control of Genetic Information" in (G.J. Annas and S. Elias, eds.) *Gene Mapping: Using Law and Ethics as Guides* (New York: Oxford University Press, 1992) at 159. Several commentators, based on protecting the free flow of information, and patient and familial privacy and autonomy rights, argue that the principle of physician-patient confidentiality should be maintained for genetics: L.B. Andrews, "Torts and the Double Helix: Malpractice Liability for Failure to Warn of Genetic Risks", 1992 29 Houston L. Rev. 149; J.K.M. Gevers, "Genetic Testing: The Legal Position of Relatives of Test Subjects", (1988) 7 Medicine and Law 161.

39 [1992] 2 S.C.R. 138.

40 *Ibid.*, at 148.

41 *Ibid.*, at 150.

> The fiduciary duty to provide access to medical records is ultimately grounded in the nature of the patient's interest in his or her records. As discussed earlier, information about oneself revealed to a doctor acting in a professional capacity remains, in a fundamental sense one's own. The doctor's position is one of trust and confidence. The information conveyed is held in a fashion somewhat akin to a trust. While the doctor is the owner of the actual record, the information is to be used by the physician for the benefit of the patient. The confiding of the information to the physician for medical purposes gives rise to an expectation that the patient's interest in and control of the information will continue.

Protection of personal privacy and guarantees of confidentiality being one of the main touchstones of the physician-patient relationship, Canadian physicians are bound by a professional code of ethics and by the law to keep in confidence any information received from or about their patients in the course of the professional relationship. Rule 6 of the Canadian Medical Association's *Code of Ethics* provides as follows:[42]

> An ethical physician will keep in confidence information derived from a patient or from a colleague regarding a patient, and divulge it only with the permission of the patient except when otherwise required by law.

Other associations of professionals working in the health sector who may enter into contact with sensitive personal genetic information have drafted codes of ethics containing similar obligations of confidentiality.[43] With particular regard to genetic medicine, the Canadian College of Medical Geneticists echoes the traditional emphasis on confidentiality, but allows its fellows more latitude in terms of when disclosure might be permissible:[44]

> Fellows of the C.C.M.G. should keep information obtained from patients in confidence unless written permission for release has been given, or, unless it can be shown this is likely to produce significant detrimental effects to the health of other individuals, currently or in the future.

In all cases, a breach of confidentiality outside of an accepted yet often implicit framework could be grounds for disciplinary action before one's respective professional body.

Medical doctors in Ontario also have statutory obligations regarding the confidentiality of medical records and the information contained therein. Section 4 of the *Regulated Health Professions Act, 1991,*[45] deems the *Health Professions Procedural Code,*[46] set out in

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42 Canadian Medical Association, *Code of Ethics*, (Ottawa: CMA, 1990).

43 See for instance the Canadian Health Record Association, *Code of Ethics for Members of the Canadian College of Health Record Administrators*, (Don Mills: CHRA,1989) and Canadian Nurses Association, *Code of Ethics for Nursing*, (Ottawa: CNA, 1991).

44 Canadian College of Medical Geneticists, *Professional and Ethical Guidelines*, (Winnipeg: CCMG, 1990) art. 10.

45 S.O. 1991, c. 18.

46 *Ibid.*, sched. 2, as am. by S.O. 1993, c. 37.

Schedule 2 of the Act, to be part of each health profession Act. The Code creates uniform procedures for disciplinary action for a number of self-governing health professions, including medicine, nursing, and medical laboratory technology.[47] Each profession's area of practice or expertise, rights, and obligations are defined by its own statute, and grounds for professional misconduct are outlined in corresponding regulations.

In the case of members of the College of Physicians and Surgeons of Ontario, the regulations enacted under the authority of the *Medicine Act*[48] state:

> 1.—(1) The following are acts of professional misconduct for the purposes of clause 51(1)(c) of the *Health Professions Procedural Code*:
>
> ....
>
> 10. Giving information concerning the condition of a patient or any services rendered to a patient to a person other than the patient or his or her authorized representative or as required by law.
>
> ....
>
> (2) Despite paragraph 10 of subsection (1) it is not professional misconduct for a member to give information about a patient, including access to the patient's records
>
> (a) to a practitioner of a health profession for the purpose of providing care to the patient; or
>
> (b) to a person for the purpose of research or health administration or planning if the member reasonably believes that the person will take reasonable steps to protect the identity of the patient.

Possible consequences for this type of professional misconduct include revocation or suspension of a physician's license, or a fine of no more than $10,000.[49]

Parallel to legal provisions concerning health care workers and their professional obligations, statutes regulating certain health institutions have sections concerning the confidentiality of medical records held on their premises. For instance, the regulations enacted under the *Public Hospitals Act* provide that: [50]

> 22.—(1) Except as required by law or as provided in this section, no board shall permit any person to remove, inspect or receive information from medical records or from notes, charts or other materials relating to patient care.

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47 *Ibid.*, sched. 1.

48 S.O. 1991, c. 30, O. Reg. 856/93.

49 *Health Professions Procedural Code, supra*, note 46, s. 51(2).

50 R.S.O 1990, c. P.40, R.R.O 965, s. 22(1).

Exceptions, in this section, are provided for inspectors, coroners, and physicians or police officers working under the authority of a coroner, and designated members of the College of Physicians and Surgeons for the purpose of investigating medical care provided to a patient.[51] The regulation goes on to authorize, at the discretion of the hospital board, disclosure of information and the forwarding of copies of the full record to the attending physician or dentist, the administrator of another hospital, a person presenting a written request signed by the patient, a personal representative of a deceased patient, a parent or person who has lawful custody of an unmarried patient under the age of sixteen, a member of the medical staff but only for teaching purposes of scientific research approved by the medical advisory committee, or any person for the purposes of scientific research.[52] Similar confidentiality provisions are provided for in legislation governing mental hospitals[53] and certain independent health facilities,[54] but rules governing other types of institutions that ostensibly could have sensitive health or genetic information in their patients' or residents' files create no strict obligations of confidentiality.[55]

(c) Exceptions to the Duty of Confidentiality

Although medical confidentiality is a basic principle of medical ethics and is protected by law, it has never been considered an absolute principle. In *McInerney* v *McDonald,*[56] it was stated as follows:

> *[P]rima facie*, the patient has a right to require that professional secrets acquired by the practitioner shall not be divulged. This right is absolute unless there is some paramount reason that overrides it.

Citing Duff J. in the 1928 case of *Halls* v. *Mitchell.*,[57] Mr. Justice La Forest continued:[58]

> For example, 'There may be cases in which reasons connected with the safety of individuals or of the public, physical or moral, would be sufficiently cogent to supersede or qualify the obligations *prima facie* imposed by the confidential relation.'

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51 *Ibid.*, s. 22(2).

52 *Ibid.*, s. 22 (6).

53 *Mental Health Act*, R.S.O. 1990, c. M.7, s. 35.

54 *Independent Health Facilities Act*, R.S.O. 1990, c. I.3, ss. 37-38.

55 See for instance, *Private Hospitals Act*, R.S.O. 1990, c. P.24, *Homes for Special Care Act*, R.S.O. 1990, c. H.12.

56 *Supra*, note 39.

57 [1928] R.C.S. 125, at 136.

58 *Supra*, note 39, at 154.

In a case concerning the unauthorized release of health records to police authorities, which was brought to the attention of the public after a public inquiry into the confidentiality of health records was held in Ontario, Mr. Justice Dubin of the Ontario Court of Appeal wrote:[59]

> Members of the medical profession have a duty of confidentiality with respect to their patients. They are under restraint not to volunteer information respecting the condition of their patients or any professional services performed by them without their patient's consent. In the absence of such consent, members of the medical profession breach their duty if they disclose such information unless required to do so by due process of law.

As the legislative and regulatory mechanisms as well as the professional obligations seen above demonstrate, the confidentiality of a patient's medical records is never absolute. Statutes and the common law may exceptionally create duties to disclose confidential medical information based upon the rationale that the public good or interest, specifically avoiding doing harm to others, sometimes justifies breaching patient's privacy. Some of the statutory sections examined above include such legal exceptions by giving a superintendent or other institutional official charged with record keeping the discretionary power to determine when files should or should not be transmitted to third parties.[60]

Aside from disclosures both explicitly and implicitly consented to by the patient, as well as those that may be necessary in legal proceedings,[61] two types of exception to the duty of confidentiality retain our attention. The first pertains to statutory duties mandating that a physician report, for purposes of public safety or public health, certain medical conditions, should they be found to affect any patient. For instance, the *Highway Traffic Act*[62] imposes a duty upon any physician treating a patient with a condition impairing their capacity to operate a motor vehicle, to report it to the proper authorities. Similarly, the *Health Protection and Promotion Act*,[63] lists a number of reportable diseases, most of them communicable or

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59 *Solicitor General of Canada* v. *Royal Commission of Inquiry into the Confidentiality of Health Records* (1981), 38 N.R. 588 at 608. The case was appealed to the Supreme Court of Canada, but this statement was not in dispute and was quoted with approval by Laskin, C.J. in *Solicitor General of Canada* v. *Royal Commission of Inquiry into the Confidentiality of Health Records*, [1981] 2 S.C.R. 494 at 500. See also *R* v. *Ross (K.)* (1993) 121 N. S. R. (2d) 242; 335 A.P.R. 242 where the court granted an order for discovery of a psychiatrist's medical file despite the complainant's lack of consent since the public interest in avoiding a miscarriage of justice overrides any claims of privilege or privacy.

60 See for instance *Freedom of Information and Privacy Act, supra,* note 31 at s. 21(2) and *Public Hospitals Act*, *supra*, note 50, at s. 22(6).

61 There has been much debate surrounding doctor-patient privilege in the courtroom as well as the accessibility of medical records for evidentiary purposes. For a recent survey of the topic see the decision of L'Heureux-Dubé J. in *Frenette* v. *Metropolitan Insurance Co.*[1992] 1 R.C.S. 647 at 687-694.

62 R.S.O. 1990, c. H.8, s. 203; R.R.O. 1990, reg. 558 & 560. See *Toms* v. *Foster*, Ontario Court of Appeal, No. C9869 June 30 1994 where two doctors were held partially responsible for an automobile accident caused by their patient after they had determined that the patients health rendered it too dangerous for him to drive but neglected to so inform the authorities. The obligation to inform, under article 177 of the *Highway Traffic Act* was held to be imperative and not merely discretionary.

63 R.S.O. 1990, c. H.7.

contagious, thus enabling the department of health to monitor a particular situation and to protect adequately members of the community.

Secondly, and more relevant to the questions raised by genetic test results and conditions, are those sporadic and narrowly defined exceptions created by the common law. Aside from the statutory exceptions to the duty of confidentiality, disclosure of psychiatric illness when a member of the public may be seriously put in jeopardy is the most discussed example of a physician's overriding duty to warn or to disclose. Discussions of the physician's duty to warn have also recently centered around disclosure of a sexual partner's HIV-positive status.

In the case of *Tarasoff* v. *Regents of the University of California*,[64] a psychiatrist was held responsible for not warning his patient's intended victim of his murderous intentions. The California Supreme Court found that, once a therapist determines that a patient poses a foreseeable threat to the safety of others, he or she must take reasonable steps to warn the intended victims, if they are identifiable. The duty to warn thus overrides the health care provider's duty of confidence but exists only in cases in which the disclosure of confidential information can prevent serious harm. According to the California Court of Appeal, circumstances creating a duty to warn were the physician's special relationship with the person who could cause harm to another, the foreseeability and degree of certainty that harm might occur, the closeness between the defendant's behaviour and the harm suffered by the victim, and the ability to identify the person at risk.

The principles developed in *Tarasoff* have not been much elaborated upon in Canadian courts, but a similar finding was made by the Supreme Court of Canada in the case of *Lawson* v. *Wellesley Hospital*.[65] Two cases in Alberta, involving psychiatric patients and their attending physicians, have also cited similar principles in order to conclude liability on the doctor's part had he or she not compromised confidentiality to warn of impending dangers, usually once the patient was at large.[66]

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64 551 P. 2d 334 (Cal. 1976) (Hereinafter *Tarasoff*).

65 [1978] S.C.R. 893, 76 D.L.R. (3d) 688. A hospitalized mental patient was injured by another mentally ill patient and the Supreme Court of Canada held that a hospital was liable for any damages suffered "if by reason of its failure to provide adequate control and supervision injury occurred to third persons by reason of the conduct or behaviour of a patient" (at 691). Given that the hospital was found liable for the patient's behaviour, arguably, where a patient presents a significant risk to an identifiable third party, a health care professional would be permitted or even required to warn identifiable persons at risk of injury.

66 It is unclear whether *Tarasoff* has been accepted into Canadian law or whether it has only been incorporated into Alberta Law. See *Tanner* v. *Norys*, [1980] 4 W.W.R. 33 where a patient brought an action against a psychiatrist for false arrest and imprisonment on the grounds that the psychiatrist had wrongfully attempted to have the patient committed to a mental institution (based on the doctors belief that the patient presented a risk of harm to an identifiable third party). The Court held that the psychiatrist was not liable, that he acted reasonably, and further suggested that he might have incurred liability to the third party if the patient had actually carried out his threat; and *Wenden* v. *Trikha*, (1992), 8 C.C.L.T. (2d) 138, aff'd (1993),14 C.C.L.T. (2d) 225 (Alta. C.A.); leave to appeal to S.C.C. denied (1993), 17 C.C.L.T. (2d) 285 where a psychiatric patient fled from a hospital, drove his car through a red light, and injured a third party. The third party

The common law duty to warn overriding the physician's duty of confidentiality may extend to informing individuals as to their sexual partner's infection with HIV or AIDS. In the recent Ontario Case of *Pittman Estate v. Bain*,[67] (now on appeal), one of the issues before the Court was whether a physician had a duty to warn his patient's spouse of his patient's exposure to HIV infection. The Court did not rule on this question since it found the physician liable in negligence for failing to inform his patient of the exposure (the Court having determined that had the physician duly notified the patient, the patient would have warned his wife), and liable for damages that resulted from that negligence, including his wife's HIV infection. Although the question of whether the physician owed an independent duty to the wife was not addressed, it is likely that a physician will have a duty to disclose a patient's HIV status to persons at risk where the patient refuses to do so. The Canadian Medical Association, in spite of its traditional stand on the confidentiality of health information, has advised medical doctors that "disclosure to a spouse or current sexual partner may not be unethical and indeed, may be indicated when physicians are confronted with an HIV-infected patient who is unwilling to inform the person at risk".[68]

HIV infection is currently a reportable disease under the *Health Protection and Promotion Act,*[69] and Ontario has a contact tracing program in which the named sexual or needle-sharing partners of an HIV positive person will be notified.[70] Such a program thus removes from physicians the pressure of making the delicate moral and ethical choice to

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brought an action in negligence against the treating psychiatrist and the hospital. The Court held that the psychiatrist and hospital were not liable as the third party was not within "requisite proximity" since there was no reason to believe that the patient presented a risk to others. See D.M. Smith, "*Wenden* v. *Trikha* and Third Party Liability of Doctors and Hospitals: What's Been Happening to *Tarasoff* ", (199) 4(2) Health Law Review 12-25 who notes that the *Tarasoff* case has been restrictively interpreted and that, in general, Canadian courts have been reluctant to allow for any expansion of liability in the medical negligence area of the law.

67 (1994), 112 D.L.R. (4th) 257). See also Walker v. *York Finch General Hospital* (1995) 23 O.R. (3d) 248 where the court (on a pleading amendment) found a duty to warn of the risk of HIV infection. On the topic of AIDS disclosure generally, see D.G. Casswell, "Disclosure by a Physician of AIDS-Related Patient Information: An Ethical And Legal Dilemma " (1989), 68 *Can. Bar Rev.* 225-258.

68 Canadian Medical Association, A CMA Position: Acquired Immunodeficiency Syndrome (1989), 140 *Can. Med. Ass. Jo.* 64A. Similarly, the General Medical Council, the British medical profession's guiding body, produced updated guidelines on the duties of a doctor which state that where a patient who is HIV positive or has AIDS has withheld consent "the doctor may consider it a duty to seek to ensure that any sexual partner is informed, in order to safeguard such persons from infection". However, the Australian Medical Association, in late 1995, decided not to press ahead with its proposed plans to allow doctors to breach confidentiality if patients refuse to tell their sexual partners that they are infected with HIV or have AIDS. See Editorial, "Maintaining Confidentiality" (1995) 346 The Lancet 1173 which argues that allowing such disclosure will create "an atmosphere of poisonous mistrust between doctor and patient" and the "[d]octors must remain responsible to their patients before all else".

69 *Supra*, note 63.

70 Ontario Law Reform Commission, *Report on Testing for AIDS* (Toronto:OLRC,1992) at 87.

breach confidentiality and personally inform such a partner, since the law places the burden of disclosure on the local medical officer of health.[71]

In cases in which potential situations of harm to third parties might exist, health care providers find themselves in a difficult dilemma as to what values should prevail: the statutory and professional duty to preserve medical confidentiality or the common law duty to prevent harm? In making such determinations about the disclosure of general medical and (now) genetic information, they walk a delicate ethical and legal line.

(d) Legal Remedies for Breach of Confidentiality

In Quebec, the right to privacy has been granted quasi-constitutional status by virtue of its inclusion in the *Charter of Human Rights and Freedoms*.[72] In addition, article 37 of the new 1994 *Civil Code* provides that any person that compiles a medical file on another must have a serious and legitimate interest and must take care not to interfere with the reputation and private life of the other. In 1993, the National Assembly adopted an *Act Respecting The Protection of Personal Information in the Private Sector,*[73] which elaborates upon the rights and obligations resulting from this and related provisions of the *Civil Code*. It is interesting to note that, under Québec legislation, in spite of an individual's refusal to give access to medical information during his or her lifetime, "persons related by blood to a deceased user may be given communication of information contained in his record to the extent that such communication is necessary to verify the existence of a genetic or hereditary disease".[74]

In common law jurisdictions, four provinces have enacted legislation creating a broad statutory right to privacy. Saskatchewan,[75] British Columbia,[76] Manitoba[77] and Newfoundland[78] have adopted privacy acts in order to create a tort actionable without proof of damage. As of yet, there is no similar statutory and actionable right to privacy in Ontario. The best legal remedies available at common law for any invasion of privacy or breach of

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71 O. Reg 490/85. See the case of Canadian AIDS Society v. Ontario, Ontario Court of Justice (General Division), 4 August 1995, court file no 4581/94 as yet unreported where the Canadian AIDS Society (CAS) failed in its attempt to prevent disclosure to donors and notification to the Ontario Ministry of Health of HIV status where donors did not specifically request their results. The court concluded that a "positive medical finding" triggered a reporting obligation as well as an obligation of disclosure to the donors regarding this devastating but vital information.

72 R.S.Q. 1977, c-12, s. 5 and s. 9.

73 L.Q. 1993, c. 17. This followed the adoption of the *Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information*, R.S.Q, c. A-2.1 in 1982.

74 *Act Respecting Health Services and Social Services*, S.Q. 1991, c. 42, art. 23.

75 *Privacy Act*, R.S.S. 1978, c. P-24.

76 *Privacy Act*, R.S.B.C. 1979, c. 336.

77 *Privacy Act*, R.S.M. 1970, c. 74.

78 *An Act Respecting Personal Privacy*, S.N. 1981, c. 6.

confidentiality, in a medical context or otherwise, remain actions for defamation, breach of contract, breach of fiduciary duty, or breach of confidence.[79]

As early as a decade ago, it was noted that the common law actions available to litigants in Ontario did not have enough of a deterrent effect upon those who might consider breaching confidentiality and were not designed to compensate the victim adequately, if at all, for damage. Furthermore, the cost of litigation could well deter a person from launching a suit at all.[80] A recommendation was thus made that a statutory right of action, actionable without proof of damage, and with a minimum statutory recovery of $10,000, should be created in Ontario.[81]

While the province of Ontario has long stated its intention to enact omnibus legislation covering the security of personal data pertaining to health or other matters, held in private sector records, there is no such law at the moment . Proposed legislation on health care information access and privacy would apply to all health care practitioners and any other persons or institutions that hold health information about an individual. Such a law would regulate the purposes for which health information would be collected, retained, or disposed of. It would clarify and strengthen principles of confidentiality and create strict and uniform conditions for disclosure, usually with the informed and written consent of the patient. Furthermore, the statute would be enforced by granting individuals a right to sue if their heath information has been disclosed in violation of the law. The legislation would provide for additional damages, up to a maximum of $5000, should the violation result from willful or grossly negligent conduct.[82] These general reforms, complimented by those made in the three specific contexts explored below, should go far to ensure the security of genetic data as it may exist and come to be included in health records.

3. GENETIC PRIVACY AND THIRD PARTY CLAIMS TO GENETIC INFORMATION

It has been noted that "until personal information has been collected by someone else, it is truly private".[83] In terms of genetic privacy, informational self-determination can be ensured first and foremost by allowing individuals the faculty to choose whether or not to undergo testing, thus granting them a right to *not know* their own genetic information. Indeed, the Privacy Commissioner of Canada made a recommendation to the effect that "persons should have a reasonable expectation of genetic privacy. There should be no

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79 S. Rodgers Magnet, "Common Law Remedies for Disclosure of Confidential Medical Information" in *Issues in Tort Law* (Toronto: Carswell, 1982) 265.

80 *Ibid.*, at 298.

81 *Ibid.*

82 Ontario Ministry of Health, *Principles for Proposed Legislation on Health Care Information Access and Privacy,* unpublished, December 1991. See, also, A. Cavoukian, "Application and Scope of the Proposed New Law", (1992) 2 *Health Law In Canada,* at 153.

83 Oscapella, *supra*, note 19, at 174.

mandatory genetic testing at the behest of the state or the private sector. Governments and the private sector should not oblige persons to learn their genetic traits or disorders."[84]

The common law principle that "every human being of adult years and sound mind has a right to determine what shall be done with his own body"[85] should go far to prevent anyone from being tested against their will.[86] Furthermore, should a mandatory genetic testing program be run under the supervision of the state, it would, in all likelihood, be deemed to infringe upon the right to liberty and security of the person in section 7 of the *Charter,*[87] as it has been held that "the common law right to determine what shall be done with one's own body and the constitutional right to security of the person can be treated as coextensive".[88]

The ramifications of the right not to know one's genetic information extends beyond the right to refrain from testing. Although the notion of genetic privacy encompasses respect for both autonomy and choice, it is questionable whether such a right is absolute. The right not to know can conflict with the right of other family members to know their genetic status, and may thus be limited to the extent that other family members or offspring might be at risk.[89] This undoubtedly puts increasing pressure on an individual to "know" his genetic status even after consciously deciding not to learn this information.

Regardless of potential conflicts with other family members, authorities in Europe have extended the right not to know to allowing individuals to ask, once testing has been performed, that test results not be divulged to them.[90] No such extension has been discussed in the North American context. Whether an individual is advised of test results or not, the fact

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84 Privacy Commissioner of Canada, *Genetic Testing and Privacy,* (Ottawa: Minister of Supply and Services, 1992) at 86.

85 *Schloendorff* v. *Society of New York Hospital* (1914), 211 N.Y. 125. The power to consent to treatment was recently reaffirmed in *Malette* v. *Shulman* (1990), 72 O.R. (2d) 417 (C.A.), aff'g (1987), 63 O.R. (2d) 243 (H.C.) and *Fleming* v. *Reid* (1991) 4 O.R. (3d) 74 (C.A.); rev'g (1990), 73 O.R. (2d) 169 (Dist. Ct.).

86 The disclosure of test results to relatives relates directly to the issues of mandatory testing for the benefit of a relative if the purpose of such compulsory testing is to provide beneficial information to the relative.

87 *Supra*, note 22. See, also, Sonia M. Suter, "Whose Genes are These Anyway? Familial Conflicts over Access to Genetic Information" (1993) 91 Michigan L. Rev. 1854, at 1868 -1876 who argues that decisions to have genetic testing should be treated as a fundamental privacy right and that compulsory testing should be considered unconstitutional for both incurable and curable diseases.

88 *Fleming* v. *Reid*, *supra,* note 85, at 88.

89 See Karen Lebacqz, *supra*, note 19, at 44 and Mark S. Frankel and Albert H. Teich, "Ethical and Legal Issues in Pedigree Research" in (Frankel and Teich, eds.), *The Genetic Frontier: Ethics Law and Policy* (Washington: American Association for the Advancement of Science, 1994), at 22. For instance, arguably an adult at risk for a severe, lethal genetic disease should be tested if there are children in the family or if they contemplate having children.

90 See, for instance, Swiss Academy of Medical Sciences, "Medical-Ethical Guidelines for Genetic Investigations in Humans", *supra*, note 14, guideline 3.4; European Parliament, *supra*, note 7; Health Council of the Netherlands, *supra*, note 11 and Comité consultatif national d'éthique pour les sciences de la vie et de la santé, *supra*, note 14.

that the genetic information collected may be relevant to family members poses particular ethical and legal challenges for those entrusted with the results. Two issues arise in this context. Does the physician have a duty to inform these relatives of their genetic risk? If there is no such duty, do practitioners have a privilege to warn relatives that would excuse them from liability for breaching confidentiality?[91]

(a) Biological Relatives

As we have noted, the most compelling confidentiality dilemma created by genetic information is that of disclosure to similarly affected relations. As genetic disease is passed down transgenerationally through a family tree, although not always in the same patterns, a genetic susceptibility or condition affecting one individual may be shared by siblings and children. Thus, information obtained through the testing of one person may pertain to and be of vital concern to several. A physician or geneticist, faced with the refusal of a patient to communicate genetic test results to family members who are potentially affected and at risk for harm should they not be informed, may feel a positive duty to override his or her obligations of confidentiality in order to warn affected relatives.[92] In fact, since genetic information about a patient has potential to benefit that entire patient's family, the attending physician may question why that patient should have a right to prevent disclosure of the information. The physician may see the patient's genetic profile as "family property" and if the information is treated as such, that physician may be in conflict between his duties to the family and to the patient.[93] This dilemma is unique to genetic medicine and as such may warrant a revision of the traditional duties or confidentiality.

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91 These issues were posed by Nancy Park and Bernard Dickens, in "Legal and Ethical Issues in Genetic Prediction and Genetic Counselling for Breast, Ovarian and Colon Cancer Susceptibility" (1995) Critical Choices: Ethical, Legal and Social Behavioural Implications of Hereditable Breast, Ovarian and Colon Cancer (Background Papers, International Research and Policy Symposium, Toronto, April, 1995) 61, at 70.

92 Where the physician or geneticist has reason to believe that the relative is at higher risk than the general population of being affected by a genetic disorder and the disorder is highly likely and treatable or preventable, many professionals would overrule a patient's refusal to disclose and would inform a relative; See Committee on Assessing Genetic Risks, Institute of Medicine, *Assessing Genetic Risks: Implications for Health and Social Policy*, (Washington, DC: National Academy Press, 1994) at 18. However, see Annas et. al., *supra*, note 18 (see Appendix 142-65) where the proposed Genetic Privacy Act makes *no exception* that would permit a health care professional to warn genetic relatives who may be at risk for developing a genetic condition since it is difficult if not impossible to set boundaries on such an exception. This "no exception rule" is seen to maximize the privacy between individuals who receive services that result in private genetic information and their health care providers. It is also considered to place the responsibility for informing relatives of their potential genetic risks on the family member who has such knowledge, which is where they believe it morally belongs.

93 J.K.M. Gevers, *supra*, note 38, at 163 presents this as a possible alternative to patient-doctor confidentiality but ultimately rejects this approach arguing that: "[t]he infringements of the principle of confidentiality would be potentially unlimited, partly because it may be impossible to draw the line between medical information that is relevant to genetic counselling and information that is not relevant, and partly because in the future ever more diseases will be found to contain hereditary components".

In a 1985 Canadian survey of geneticists,[94] it was found that very little consensus exists as to which cases merit unauthorized disclosure to biological relatives. Roughly half of those surveyed responded that they would, in spite of their patient's clear refusal, inform relatives at risk of carrying the gene for Huntington disease or for hemophilia A. Comparatively, in a subsequent 1994 survey,[95] there was a clear trend toward maintaining confidentiality and avoiding disclosure to relatives who do not ask. Notwithstanding this emerging trend, it is clear that the boundaries regarding the duty to preserve confidentiality, and the notion of what constitutes serious harm, is highly subjective. The need for guidance should some limited provision for disclosure in the context of genetic medicine be made, is thus all the more apparent.

Arguments have been made that the duty to warn elaborated in *Tarasoff*[96] may be applicable in the context of genetic testing. However, to date, no courts have held that there is a duty to warn relatives of patients that they may be at risk of a genetic disorder.[97] It is unlikely that the courts will do so in the future given that the cases recognizing a duty to warn identifiable third parties of a threat of violence can be distinguished from the duty to warn at risk third parties about potential genetic risk.

The crucial difference between cases of disclosure of psychiatric illness or HIV infection and those of disclosing genetic illness to relatives who may be affected, lies in the nature of the harm for which they are at risk. In the former cases, it is the patient's actions that are likely to harm others; whereas in the case of genetic susceptibility, the patient is not putting relatives at risk by carrying the gene.[98] Many agree with this position and argue that protecting people from violence is distinct from informing them that they may be at risk for a genetic disease.[99]

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94 D.J. Roy and J.G. Hall, "Ethics and Human Genetics in Canada", in D.C. Wertz and J.C. Fletcher, eds., *Ethics and Human Gentics: A Cross-cultural Perspective* (Heidelberg: Springer-Verlag, 1989) 119.

95 D.C. Wertz, "Professional Perspectives: A Survey of Canadian Providers", (1995) 3 Health Law Journal 59--130, at 99. The percent of respondents who would maintain confidentiality almost doubled between 1985 and 1994.

96 *Supra*, note 64.

97 L.B. Andrews, "Medical Genetics: A Legal Frontier" Chicago, Illinois: American Bar Foundation, 1987, at 197; and Park & Dickens, *supra,* note 91, at 71.

98 Park & Dickens, *ibid.*

99 See J.K.M. Gevers, *supra,* note 38, at 164. However, see, also, J. Miller "Physician-Patient Confidentiality and Familial Access to Genetic Information", (1994) 2 *Health Law Journal* 141, at 148, where the author notes that there are a number of similarities between the two cases: a special relationship exists between the physician and the patient, the third party is identifiable, there is no special relationship between the physician and the third party, the information to be disclosed is confidential, and there is an opportunity for the prevention of harm. She does point out that the cases may diverge if a duty to warn extends only to protecting a third party from possible violence as such a requirement would not support the disclosure of genetic information; and if the patient must pose a *serious* danger of violence then the duty to warn may also

A number of factors need to be considered when deciding whether disclosure is or is not warranted: the seriousness of the defect, the likelihood that the relative has the genetic defect, whether or not the defect will be detected by other means, the availability of treatment, and the seriousness of the harm to be suffered by third parties.[100] It is also important to bear in mind that the principles derived from *Tarasoff,*[101] should they be deemed to be applicable to genetic test results in a familial context, require that disclosure be made to avoid harm, and not simply because the information would be of benefit to a family member, in so far as they could better plan their lives, their finances, or make more informed reproductive choices.[102]

One must also consider the very real possibility that, within a group of relatives, knowledge may constitute a greater harm and that a medical doctor's benevolent intentions could backfire in the case of those individuals who might prefer not to know. It can be argued that unsolicited, sensitive information should not be forced upon any person. Indeed, this position is aligned with the Privacy Commissioner of Canada's recommendation that no person be forced to learn their genetic traits or disorders.[103] While this proposal was made in the context of mandatory testing, a strong argument could be made that knowledge of one's genetic makeup, or susceptibility to disease, should not be imposed upon a person in any manner, particularly in cases in which the information is derived from the test results of a related individual and through no initiative of one's own, or in which the condition is untreatable.

Amongst the proposals made to resolve confidentiality dilemmas raised by genetic test results in the familial context, is the suggestion that patients be informed that the outcome of testing may warrant warning at risk relatives. Health care providers screening for genetic conditions would thus inform, in advance, their patients of this eventuality.[104] A proposed "genetic Miranda warning", would inform the patient of which circumstances would result in disclosure before testing, regardless of the patient's intentions in that regard. Such a forewarning would thus permit the patient to refuse testing altogether or to seek medical advice and services elsewhere: [105]

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not extend to disclosure of genetic risks because there may only be a possibility [i.e. in common multifactorial diseases] that the family member carries the genetic disease disclosed in the patient's profile.

100 R. Macklin, *supra*, note 38, at 163.

101 *Supra*, note 64.

102 R. Macklin, *supra,* note 38, at 164.

103 Privacy Commissioner of Canada, *supra*, note 84, at 86.

104 One could go further and make access to testing conditional upon prior agreement to inform any relatives at risk when such information would be required to prevent serious harm. See the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Screening and Counseling for Genetic Conditions*, (Washington, DC: Government Printing Office, 1983) (Hereinafter *President's Commission*) at 43.

105 R. Macklin, *supra,* note 38, at 164.

> To inform patients in advance that some circumstances may arise in which genetic information will be disclosed is not likely to jeopardise the physician patient relationship, so long as the physician assures the patient of the presumption of confidentiality and outlines the exceptions to that presumption.

However, this approach gives rise to several real possibilities. A person may avoid getting the care he or she requires by not undergoing diagnostic testing and two classes of physicians could emerge—those who respect confidentiality in all cases, and those who breach it in certain extreme and fairly well delineated situations. In spite of the fact that any exception created to the duty of confidentiality will necessarily operate on a case by case basis, it would nonetheless be desirable that most practitioners in this field of medicine identify standard situations and genetic conditions as meriting disclosure to affected family members.

In 1983, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research proposed guidelines as to when patient confidentiality could be overridden. The Commission proposed that disclosure should take place when: [106]

1. Reasonable efforts to elicit voluntary consent to disclosure have failed.

2. There is a high probability that harm will occur if the information is withheld, and the disclosed information will actually be used to avert harm;

3. The harm that would result to identifiable individuals would be serious; and

4. Appropriate precautions are taken to ensure that only the genetic information needed for diagnosis and/or treatment of the disease in question is disclosed.

These recommendations have been supported by the Science Council of Canada.[107] Further, it should be noted that these principles do not imply that there is a legal duty to warn, they simply set out circumstances in which it would be permissible to do so. Accordingly, disclosure without consent is justified where the information is both significant and useful to the affected third party relative. The information is significant if it reveals that the relative is at a substantially higher risk of suffering from a serious and likely undetected genetic disorder. The information is useful if it can be used to seek available treatment or avoid harmful stimuli. While the guidelines suggest that disclosure might be justified under specific conditions, it is unclear whether such disclosure is also required.

If confidentiality is breached (under the conditions set out by the President's Commission), it is unlikely that legal liability will follow, given that the courts have recognized that if disclosure is performed to protect a person perceived to be in imminent

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106 See *President's Commission*, *supra*, note 104.

107 *Genetics in Health Care, Report 42,* Ottawa, Minister of Supply and Services Canada; 1992.

peril of harm and is the minimum disclosure necessary to serve that purpose, it may be considered legally excusable.[108]

In terms of public policy, it has been remarked that health care professionals who favour contacting relatives, even if only in particularly compelling cases, may unwittingly create an expansion of standards of care. "Exercising a right to disclose may ultimately set a standard creating a duty to disclose."[109] Accordingly, the ramifications of such a duty could involve tracking down all close relatives possibly affected by a genetic condition and could become particularly burdensome as the genetic component and tests for common diseases come to light. The liability of a physician who fails to contact a relative or spouse who is later harmed would also have to be considered.[110]

(b) SPOUSES

A similar dilemma regarding breach of patient confidentiality in the context of genetic medicine arises with disclosure to spouses and reproductive partners. Genetic conditions and disease being transmitted vertically rather than horizontally, spouses are not at risk of carrying the genetic condition of their mate, but nonetheless genetic test results may be of interest to spouses and life partners for the purpose of making informed reproductive choices.[111] While there is no risk to them personally, there is a risk that existing or future children could be affected.[112] In most cases, the tested individual will inform his or her partner and in fact many couples undertake genetic counselling together. However there may be cases in which the spouse refuses to disclose test results. In such an instance, the fact that no immediate or physical harm to the spouse is being averted may be an important consideration in determining that individual's right to know, and may diminish considerably that person's claim to being informed.

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108 Park & Dickens, *supra,* note 91, at 72.

109 L.B. Andrews, "Legal Aspects of Genetic Information", (1991) 644 *Yale J. Biol. & Med.* 29, at 34.

110 L.B. Andrews, *Ibid.* See also Miller, *supra*, note 99 who agrees with Andrews and argues that if disclosure of confidential genetic information about a patient over a patient's objections is ultimately covered by the duty to warn principle, then the physician could be sued by the family member for the failure to disclose and prevent harm. See, also, *supra,* ch. 8.

111 The spouse of an individual diagnosed as having the allele for a serious recessive disorder might claim that a physician has a duty to share that information in order to facilitate reproductive decision making. A few courts have allowed physicians to disclose medical information about an individual in order to protect a spouse or potential spouse (see *Berry* v. *Moensch* (1958) 331 P.2d. 814 (Utah)) but this has often been based upon allowing disclosure of communicable diseases where risk of transmission is high. Since genetic disorders are not communicable, arguably, arguments based on allowing disclosure of communicable diseases (i.e. venereal diseases or AIDS) to spouses or life partners are muted. See *supra*, note 92, at 17.

112 *Ibid.* For example, an argument could be made that where a husband learns that he has Huntington disease, a wife could have some claim to this information since if she and her husband have children, there will be a 50% chance that each child will inherit the disease. Moreover, each spouse could have a claim to the information that the other was a carrier of a single gene for a recessive defect. It is likely however that it is only a moral claim to the information and not a legal one.

The American Institute of Medicine's Committee on Assessing Genetic Risks recommended that health care providers not reveal genetic information about a patient's carrier status without authorization. It noted that the harm envisioned in cases in which confidentiality should be breached has to be substantial and imminent, and that the reproductive partner's claim to eventual harm due to the possibility of bearing a child with a genetic disorder did not meet this standard.[113]

It has been noted that "[o]n the ground of preserving the life and welfare of the family, it may be argued that every family member has the general obligation to inform other relevant family members of matters relating to their welfare and more broadly to the value of preserving the family".[114] The case of disclosure to spouses where there is no direct harm involved should be analyzed in light of a fiduciary duty, which may exist between life or reproductive partners. It is likely that, in all but extreme cases, a compelling moral obligation on the part of patients to share genetic information within a familial or marital context[115] will ensure that, in the vast majority of cases, physicians will not have to contemplate breaching their duties. However, there remains a pressing need for legislative intervention in the areas of genetic and health data protection as well as guidance with regard to permissible breaches of confidentiality in the context of genetic medicine.

4. CONCLUSION AND RECOMMENDATIONS FOR REFORM

The development of genetic testing and the information derived therefrom raises serious concerns about privacy and confidentiality. These concerns are exacerbated by the ability of genetics to predict health risks not only for the individual tested, but for blood relatives and potential offspring. While genetic information is clearly unique from all other information, it can be subsumed within the context of medical information generally.

As such, legislation must establish uniform and comprehensive privacy and confidentiality protections for all medical information.[116] In order to ensure the privacy of

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113 *Ibid.*, at 27. See, also, Charles Ngwena and Ruth Chadwick, "Genetic Diagnostic Information and the Duty of Confidentiality: Ethics and Law", (1993) 1 Medical Law International 73, at 86 who point out that while a spouse or partner may be denied the capacity to make an informed reproductive choice, it is not clear that harm to choice is itself sufficiently serious to warrant disclosure.

114 Sumner B. Twiss, Ethical Issues in Genetic Screening: Models of Genetic Responsibility in (Daniel Bergsma ed.,) *Ethical Social and Legal Dimensions of Screening for Human Genetic Disease* (New York : Symposia Specialists; Stratton Intercontinental Medical Book Corp., 1974) at 255. However, see *Saul.* v. *Himel* (1994) 22 C.C.L.T. (2d) 292 where the court found that no special relationship between a husband and wife existed and that a wife had no duty to her husband upon conception or subsequently during cohabitation to disclose to him the existence of an extramarital affair by her the result of which might be that the husband would not be the biological father of a child born to that wife.

115 D.C. Wertz and J.C. Fletcher, "Proposed an International Code of Ethics for Medical Genetics" (1993) 44 *Clin. Genet.* 37, at 41.

116 See L.O. Gostin, "Genetic Privacy", (1995) 23 Journal of Law, Medicine & Ethics 320-330, at 326 who notes that the enactment of genetic specific privacy legislation could create inconsistencies in the rules governing dissemination of health information; and since "the flow of medical information is rarely restricted to particular diseases and conditions", "comprehensive legislation on health information privacy,

such information, we have concluded that effective mechanisms for enforcement, which include a privacy right of action by the aggrieved party and significant penalties for persons or institutions who breach the legal requirements, are necessary.

Notwithstanding the implementation of such legislation, genetic privacy in its strictest sense is probably not feasible, either technically, socially, or politically.[117] When allegedly private information can not also claim to be personal information (as the information is not solely about the individual tested), the possibility of maintaining privacy becomes rather unlikely. Moreover, as genetic information becomes part of a person's medical record, and as computerization becomes more prevalent, an increasingly wide range of persons will have access to the genetic information. As a result, a privacy claim may be difficult to assert in the area of genetic information.

The long standing history of preserving the legal duty of confidentiality is also not absolute; sometimes important concerns override the duty and create a privilege to reveal otherwise confidential information. A privilege to warn may well be permitted when serious harm can be prevented. In such instances, interest in protecting the public or third party blood relatives can outweigh the duty to preserve confidentiality. The result however, is conflict between an individual's right to confidentiality within the doctor-patient relationship and the physician's duty to warn these relatives of known risks.

The circumstances under which disclosure will or should be allowed, is a primary issue. It would be unsatisfactory to leave the matter to the discretion of physicians or geneticists, who may have varying opinions on the kind of genetic diseases that would be in the public interest to disclose.[118] Uniform, comprehensive guidelines are thus imperative.

Given that neither genetic privacy nor confidentiality are absolute, it is our view that physicians and geneticists should have a privilege to disclose genetic information to at risk blood relatives where the genetic disorder is serious, unlikely to be detected by other means, and can be used to seek available treatment. However, there should always be a presumption against disclosure. The interest in warning these relatives must be balanced against the interests of the patient. In light of the general legal framework we have examined, the Commission has concluded that legislation should be enacted providing for access to and privacy of health care information generally. Separate legislation for genetic information, in our view, could create inconsistencies in the rules governing dissemination of health information, and ultimately will become inadequate as genetic testing becomes routinely integrated into medical records. Accordingly, we recommend that legislation should be enacted to protect all health information, including genetic information, held in both public and private facilities. The Commission further recommends that this legislation should

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with explicit language applying privacy and security standards to genomic information" would be a better alternative.

117 K. Lebacqz, *supra*, note 19, at 40.

118 Ngwena & Chadwick, *supra*, note 113, at 88.

provide for the acquisition, safe storage, use, and transfer of any records, and should provide expressly for privacy and security standards of genetic information.

Informed consent, with a uniform or standardized form for authorizing disclosure, should be the norm for all but exceptional (that is, newborn screening) and urgent disclosures, which should be identified explicitly in the legislation. In addition, the legislation should include a statutory right of action, with severe penalties for any breach of confidentiality or privacy with regard to a person's general medical or genetic data. Moreover, the duty of confidentiality of all health care workers, and other individuals who may come into contact with sensitive genetic data contained in health records, should be reviewed and standardized.

In light of, and consistent with, the enactment of general health care privacy legislation, the Commission recommends that there should be a presumption in favor of confidentiality and against disclosure with respect to all medical information, including genetic information. Issues of genetic testing make the enactment of the recommendations of the (1980) Krever Report all the more pressing.

The Commission further recommends that uniform testing policies should be adopted so that physicians and geneticists can advise patients when certain types of information may have to be disclosed to a spouse, relative, or third party (for example, an employer or insurer). The circumstances under which such disclosure may take place should be explained in advance of testing so that the individual can choose whether or not to be tested.

Participants in genetic testing, in our view, should be informed prior to being tested that the information derived therefrom may be relevant to family members, and we so recommend. While the patient may have a moral duty to inform at-risk relatives, at present, there is no corresponding legal duty.

The Commission recommends that legislation should not prescribe the disclosure of genetic information to high risk relatives, although physicians should have a privilege to disclose test results if they believe the interest in informing relatives strongly outweighs the interest in confidentiality.

Finally, the Commission recommends that a physician should be permitted to disclose genetic information only if the following conditions are satisfied: (1) reasonable attempts to elicit voluntary disclosure are unsuccessful; (2) there is a high probability of serious harm to an identifiable third party; (3) there is reason to believe that disclosure of the information will prevent harm; and (4) the disclosure is limited to the information necessary for diagnosis or treatment of the third party. Accordingly, where the genetic disorder is not serious, where it is likely to be diagnosed or is of relatively common knowledge, or where there is no known treatment or prevention, disclosure would not be permitted.

SUMMARY OF RECOMMENDATIONS

The Commission makes the following recommendations:

CHAPTER 4: PROPERTY RIGHTS AND GENETICS

1. Legislation should be enacted directing the courts to take an expanded approach to the characterization of human genetic material as an extension of the person, and thus crucial to his or her bodily integrity, and requiring express informed consent for any present or future use.

2. Section 11 of the *Health Care Consent Act, 1996* should be amended to expand the notion of informed consent. This requires the creation of a legal obligation for institutions and physicians to inform patients of any disposal policies or of any uses that will be made of tissue/cells removed for *diagnostic* sampling, or for *therapeutic* purposes.

3. (1) Informed consent with regard to *research* on excised tissue should be express and written, notwithstanding section 11(4) of the *Health Care Consent Act, 1996,* which provides that consent may be express or implied.

   (2) Anonymous epidemiological research should be exempt from the requirement in paragraph (1).

4. (1) Diverse forms should be created by the appropriate regulatory bodies in order to obtain the signature of the research subject with regard to such research.

   (2) Such forms should encompass a number of different actual and prospective options for the different types of research and banking of excised tissue/cells in order to best meet the personal present and future needs and wishes of the patient/participant in that regard.

   (3) Any personal, professional, financial or other interest of the physician/researcher should be disclosed.

5. Blood relatives should have access to stored DNA where necessary for their own medical diagnosis.

6. The transfer of any tissue/cells in exchange for valuable consideration should be prohibited.

7. (1) Regardless of the approach ultimately adopted, a regulatory body should be established in order to monitor and control the establishment and activities of any private or public DNA banking facility.

(2) The regulatory body would certify such establishments, and would create and enforce minimal standards for quality assurance in terms of services and personnel.

CHAPTER 5: DNA PATERNITY TESTING

8. Pursuant to section 11(c) of the *Children's Law Reform Act,* DNA testing facilities should be monitored and accredited in order to ensure that laboratory standards and testing methodology for the purposes of section 10 of the Act are uniform and of high quality.

9. DNA identity testing should be permitted only with leave of a court of competent jurisdiction.

10. The receipt of social assistance for economically disadvantaged mothers should not be dependent upon the participation of women and children in DNA testing.

11. (1) The courts should exercise caution in allowing leave for testing.

(2) The interest of the child should be paramount in the decision.

(3) The interest of the child, with regard to genetic identity testing, should take into account the following factors:

(a) the child's past and present relationship with his or her parents;

(b) his or her physical, mental, and emotional needs;

(c) the stability of the child's current home environment (whether there is an ongoing family unit); and

(d) the child's knowledge of the paternity dispute.

12. In cases in which a declaration of paternity under section 4 of the *Children's Law Reform Act* has already been made, a time limitation should be enacted in order to limit the application of section 6, which permits the courts to reopen a case and revise their decision where new (in this case DNA) evidence is available and might result in a different verdict.

CHAPTER 6: INSURANCE TESTING

13. There should be a five-year moratorium on requests for genetic testing, questions about genetic conditions, and requests for access to genetic information in medical records, to provide an opportunity for all concerned to develop sound policies.

14. (1) During the five-year moratorium, the insurance industry should establish a requirement of actuarial fairness so as to develop standards of accuracy, validity, and predictive value for the use of genetic tests on insurance.

(2) In order to incorporate actuarially sound genetic knowledge in underwriting practices legitimately, further genetic epidemiological studies should be conducted so that premiums charged reflect true risk.

(3) General recommendations regarding general selection and risk classification criteria should be approved by the Insurance Commissioner, and publicized so as to avoid adverse selection.

15. During the five-year moratorium, the insurance industry should consider creating risk pools with community rating based simply on currently obtained family histories, without requiring individual information or testing for those families or populations identified as at risk for having single gene disorders.

16. (1) As an alternative, or in addition to the above proposals, there should be a standard "no questions asked" policy, in which the amount of insurance requested is proportionate to the social and financial circumstances of the applicant, or at the very least, for a minimal amount of life insurance for all.

(2) Above the level of insurance referred to in paragraph (1), insurers should be permitted to demand access to genetic information.

CHAPTER 7: GENETIC TESTING IN EMPLOYMENT

17. The Human Rights Commission should issue an interpretive rule providing that genetic conditions, both present and future, fall within the ambit of its legislative protection.

18. The definition of the phrase "because of handicap" contained in section 10(1) of the *Human Rights Code* should be amended to add the words "or for the reason that it is believed that the person will have" to the definition, such that the definition will provide as follows:

> 10.—(1) In Part I and in this Part,
>
> ....
>
> "because of handicap" means for the reason that the person has or has had, or is believed to have or have had, or for the reason that it is believed that the person will have,
>
> (a) any degree of physical disability, infirmity, malformation or disfigurement that is caused by bodily injury, birth defect or illness and without limiting the generality of the foregoing, including diabetes mellitus, epilepsy, any degree of paralysis, amputation, lack of physical coordination, blindness or visual impediment, deafness or hearing impediment, muteness or speech impediment, or physical reliance on a guide dog or on a wheelchair or other remedial appliance or device,
>
> (b) a condition of mental retardation or impairment,

(c) a learning disability, or a dysfunction in one or more of the processes involved in understanding or using symbols or spoken language,

(d) a mental disorder, or

(e) an injury or disability for which benefits were claimed or received under the *Workers' Compensation Act.*

19. Pre-employment genetic testing should be undertaken only when it is demonstrated to be directly job-related.

20. (1) Testing should be conducted only after a conditional offer of employment is made.

(2) Criteria should be established in order to determine when individual genetic pre-employment testing is appropriate, and should include a high standard of proof that the test used is related to a *bona fide* occupational requirement.

21. (1) Specific and informed consent should be required before any type of genetic testing is performed on a worker or job applicant.

(2) Employers should be required to disclose the nature and purpose of all medical procedures performed, and to provide genetic counselling services to those who elect to undergo testing.

22. Any situation that discriminates, actually or potentially, against employees having a "genetic or other medically identified predisposition to an impairment," should be considered a violation of the existing rules prohibiting discrimination.

23. (1) The Ontario Workplace Health and Safety Agency, based on the *Human Rights Code*, should designate which genetic tests are scientifically valid and accurate in a given employment context, in order to avoid indiscriminate use of testing by employers.

(2) The tests designated pursuant to paragraph (1) should be highly relevant to health problems encountered in the particular area of activity in question, or used to detect genetic susceptibility to toxic substances.

(3) Approved and designated tests should be included in relevant regulations, and guidelines as to how testing programs are to be administered should also be established.

24. A uniform bill on health care information access and privacy should be enacted, which would apply to private and public sector employers, and outline clearly the duties of occupational physicians as well as the rules governing employer access to health information.

CHAPTER 8: MEDICAL TESTING

25. The Ministry of Health should establish regulations that prescribe minimum or appropriate standards for genetic testing, personnel training and education in the area of medical genetics, and the accreditation of genetic laboratories.

26. Physician and institutional liability to parents and children in the area of genetic testing should be left to general malpractice rules.

27. Professional associations should study the ambit of a possible duty to recall or to "look-back".

28. (1) Explicit parental consent should not be required for newborn screening for diseases that are immediately treatable but irreversible if left to be discovered clinically.

    (2) However, the banking of newborn screening data and samples should be subject to parental consent, and to quality assurance and oversight.

29. (1) Children should not be tested for genetic conditions where there are no timely medical or psychosocial benefits, or where these benefits will not accrue until adulthood (as in the case of carrier status or adult-onset diseases).

    (2) Where the balance of benefits and harms is uncertain, and the family requests testing, such requests should be presented to an ethics committee (possibly the hospital's own committee, where available) for determination.

30. Mature minors should be able to make their own decisions with regard to genetic testing, following the provision of all appropriate information, including genetic counselling.

31. Wrongful life suits by children against their parents should be prohibited by legislation.

CHAPTER 9: PRIVACY AND CONFIDENTIALITY

32. (1) Legislation should be enacted to protect all health information, including genetic information, held in both public and private facilities.

    (2) This legislation should provide for the acquisition, safe storage, use, and transfer of any records, and should provide expressly for privacy and security standards of genetic information.

    (3) Informed consent, with a uniform or standardized form for authorizing disclosure, should be the norm for all but exceptional (that is, newborn screening) and urgent disclosures, which should be identified explicitly in the legislation.

(4) The legislation should include a statutory right of action, with severe penalties for any breach of confidentiality or privacy with regard to a person's general medical or genetic data.

(5) The duty of confidentiality of all health care workers, and other individuals who may come into contact with sensitive genetic data contained in health records, should be reviewed and standardized.

33. There should be a presumption in favor of confidentiality and against disclosure with respect to all medical information, including genetic information.

34. (1) Uniform testing policies should be adopted so that physicians and geneticists can advise patients when certain types of information may have to be disclosed to a spouse, relative, or third party (for example, an employer or insurer).

(2) The circumstances under which such disclosure may take place should be explained in advance of testing so that the individual can choose whether or not to be tested.

35. Participants in genetic testing should be informed prior to being tested that the information derived therefrom may be relevant to family members.

36. (1) Legislation should not prescribe the disclosure of genetic information to high risk relatives.

(2) Physicians should have a privilege to disclose test results if they believe the interest in informing relatives strongly outweighs the interest in confidentiality.

(3) A physician should be permitted to disclose genetic information pursuant to paragraph (2) only if the following conditions are satisfied:

(a) reasonable attempts to elicit voluntary disclosure are unsuccessful;

(b) there is a high probability of serious harm to an identifiable third party;

(c) there is reason to believe that disclosure of the information will prevent harm; and

(iv) the disclosure is limited to the information necessary for diagnosis or treatment of the third party.

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